HIT Policy Committee
Final Transcript
April 13, 2011

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director
Good morning, everybody and welcome to the 22nd meeting of the HIT Policy Committee. This is a Federal Advisory Committee, so there will be opportunity at the end of the meeting for the public to make comment. Also, a transcript of the meeting will be available on the ONC Website. A reminder for workgroup members to please identify yourselves when speaking for attribution.

Let's just do a quick introduction around the table, starting on my left with Josh Seidman.

Josh Seidman – ONC
Josh Seidman, ONC.

Charles Kennedy – WellPoint – VP for Health IT
Charles Kennedy, WellPoint.

Jim Borland – SSA – Special Advisor for Health IT, Office of the Commissioner
Jim Borland, Social Security Administration. Judy, I'd like to note that this will be my last Health IT Policy Committee meeting. Greg Pace, who's our Deputy CIO, will be representing the agency in the future.

Deven McGraw – Center for Democracy & Technology – Director
That's hard to follow. We'll miss you, Jim. This is Deven McGraw, Center for Democracy & Technology.

Farzad Mostashari – ONC – National Coordinator
Farzad Mostashari. I'm the National Coordinator for Health IT.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Paul Tang, Palo Alto Medical Foundation.

David Bates – Brigham and Women's Hospital – Chief, Div. Internal Medicine
David Bates, Brigham and Women's and Partners.

Marc Probst – Intermountain Healthcare – CIO
Marc Probst with Intermountain Healthcare.

Linda Fischetti – VHA – Chief Health Informatics Officer
Linda Fischetti, Department of Veterans Affairs, representing Deputy Undersecretary Agarwal.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
Larry Wolf for Rick Chapman, Kindred Healthcare.

David Lansky – Pacific Business Group on Health – President & CEO
David Lansky, Pacific Business Group on Health.

Paul Egerman – Software Entrepreneur
Paul Egerman, Software Entrepreneur.

Connie Delaney – University of Minnesota School of Nursing – Dean
Connie Delaney, University of Minnesota.

Judy Faulkner – Epic Systems – Founder
Judy Faulkner, Epic.

Judy Sparrow – Office of the National Coordinator – Executive Director
We have a number of members on the telephone. Gayle Harrell, are you there?

Gayle Harrell – Florida – House of Representatives
Yes, I am. ..., State Representative still in Tallahassee working hard.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, Gayle. Scott White?

Scott White – 1199 SEIU – Assistant Director & Technology Project Director
I'm here. Good morning, all.

Judy Sparrow – Office of the National Coordinator – Executive Director
Christine Bechtel?

Christine Bechtel – National Partnership for Women & Families – VP
Christine Bechtel, National Partnership for Women & Families. I'll see you guys in a little bit.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, Christine. Anybody else on the telephone? All right, with that I'll turn it over to Dr. Mostashari.

Farzad Mostashari – ONC – National Coordinator
Thank you, Judy. My father-in-law always said that it's important to pick your successor, but it's more important to pick your predecessor. I chose terribly because David Blumenthal is a very, very tough act to follow, particularly in the review of David's tenure it was pretty impressive the broad range of support and applause for the unique skills that David brought to the position that really helped set the HITECH agenda and move us to the next level. Well, I'm not David Blumenthal, but I will do my best and I will continue down the path that we have set, not only in terms of the specifics but also in terms of how we approached policy making in the past two years.

A big part of that is this committee. A big part of that is the inclusive and open and transparent processes we followed and the listening. One thing that people kept saying about David was, that guy really knows how to listen, and I will try to continue that very attentive listening, that very inclusive process that I think yields the best product for the public interest. We also have to be thinking about the public interest while we listen to all the different competing and attention between different stakeholder interests, our job is to listen well and then act in the public interest, and I pledge to you that we will continue to do that with your help.

We will also have to communicate better, I think. We've done a great job listening, but I think we could have done a better job, and I hope we will do a better job in terms of communicating what the health IT agenda means for people, for providers, what does it mean for the front line staff, what does it mean for patients and consumers. So that will be, I think, an area where we will work harder to not just be good listeners but also be good communicators in terms of the vision and where we're going and what it will mean for you.

We will also continue to work with the market and to tap into the innovation and energy of the private sector, even as we work to make a more perfect market, whether that's around transparency, reducing information asymmetries, but also I think we need to understand better what's happening in the industry and in the market. So that will be, I think, a continued part of our agenda. While we do that we have to continue to watch out for the little guy. The market does some things incredibly well. It doesn't particularly look out for the little guy. That's going to be a continued role for government in this, whether

it's through the community college workforce program or the regional extension centers and so forth. That's where we'll have, I think, a great deal of continuity: listening, fostering innovation, working with the market, and watching out for the little guy.

There are three other elements to our principles that we keep talking about that we'll be doubling down on. They've always been there but we'll double down on them. I think some of these are evident in our health IT strategic plan, these directions. These are not new directions, but we'll certainly be seeing a greater emphasis in the years to come. The first is around the boots on the ground. We're moving into an intense implementation and execution phase, and now I know from personal experience implementing electronic health records in small doctors' offices in some very underserved communities and community health centers with hospital outpatient department patients how incredibly hard this work is. We're going to need to execute. We're going to need to continually improve in terms of the implementation of our programs. That will be, I think, an area of emphasis certainly in this next phase.

The second area of emphasis and redoubling is going to be, and we see this in the strategic plan, the concept of putting the patient and their interests in the center of everything we do. We see that in the quality measures work, we see that around privacy and security, moving forward finally on really getting to the point where we have more in the way of guidance, more in the way of protections. As more and more data becomes liquid, I think we owe that to the American people. Also in terms of making progress on ways we can technologically have opportunities for greater patient protection, whether it's around more granular implementation of policy, around patient preferences, through metadata, whether it's around distributed methods of having learning happening without having to centralize information, as was the vision in the PCAST Report. I think there are lots of opportunities and we'll hear some of those laying the framework for enabling the sort of approaches, including trusted intermediaries and governance in the near future.

But it also means paying more attention to and thinking more about the consumer eHealth market. A lot of the HITECH mandate is around doctors and hospitals and electronic health records. That creates, as one interpreter said to me, "data is oxygen" and there's just going to be a lot more oxygen out there in the form of electronic information for innovations in the consumer space. I think the timed cycle of innovation in the consumer space and population health management tools and patient provider communications and visualization of information and improved decision making on the part of patients, I think that can be truly explosive and disruptive innovations in a very good way there. So I think that's an area where we're going to have to, and we want to, double down.

Finally, it's in the outcomes and eye on the prize. Everything we've done, the framework for meaningful use has really been not about the technology, it's about what we want to achieve and accomplish with the technology, the framework for meaningful use around higher quality, safer, more efficient care, more care coordination, patient engagement and so forth, we're going to double down on that. Part of the reason for that is because the future, which we always said that's the arc of the future, the future is closer now than it was two years ago. In particular, the changes that have come as a result, not of HITECH, but of the Affordable Care Act, have made the alignment between health payment delivery system transformation and information, have made that alignment happen in a way that I think is unprecedented.

I was struck at HIMSS at how much discussion there is about how we can improve care coordination or population health management, the innovation in that space, not only in electronic health records themselves, but all the things that go around that to improve coordination of care. The ACO rule that recently came out had a lot in it about meaningful use and information exchange and preventing data lock-in, meaningful choice for sharing of information. That wasn't accidental. There is, quite consciously, an understanding at the federal government that these transformations on information and innovation and delivery system and innovation of payment go together to create a new opportunity for us, an unprecedented opportunity.

We're going to be hearing shortly from Peter Lee about the National Quality Strategy and about a very exciting Partnership for Patients that was announced yesterday. I think quite consciously we need to be aligning and coordinating our work in the service of the broader national health goals that are

encapsulated in that National Quality Strategy and in the Partnership for Patients. It's an incredibly exciting time because finally, finally the stars are aligned so that the information and what the information technology can provide in the service of improved quality and safety is aligned with not just what providers and hospitals want to do every day, but the payment that will enable them to be successful and thrive doing so. It's a very exciting time, and I'm honored and privileged to be working with you to help take us to the next level. Thank you.

I'm going to turn it to Paul to review the agenda, and then we actually have after that an introduction of a new member for the Policy Committee.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Actually, why don't you go ahead and do that now?

Farzad Mostashari – ONC – National Coordinator
Sure, we'll do that first. I'm very pleased to announce Dr. Josh Sharfstein, who is the Secretary of Health and Mental Hygiene for the state of Maryland, who will be joining the Policy Committee as a member. I had the privilege of working with Josh over the past couple of years, where he was the principal deputy at the FDA, and I can tell you that his deep interest in health and public health and his creativity are really amazing. His responsibilities currently include Medicaid, behavioral health and public health in the state. He has an M.D. from Harvard Medical School, and he's a really wonderful person and I think you'll really appreciate his contribution to the committee.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Great, thank you, Farzad. Just before we start with the agenda, I wanted to point out we thought that Dr. Blumenthal would be here at this meeting and we wanted to acknowledge his tremendous two years of leadership. The entire program went from zero to 60 in two years, which is totally incredible and it's a manifestation of his great leadership and the abilities that Farzad mentioned. So we certainly as a committee want to acknowledge his role in really jump starting the HIT adoption and use in achieving the outcomes that Farzad talked about.

We want to also thank you, Farzad, for a tremendously inspiring vision in terms of where the country's headed and where you would like to lead it in the HIT support. It's true that just since we last met I think the quality strategy came out, the ACO, NPRM, and then the new patient safety, just since we last met, and truly even in the words they're not only aligned in spirit, literally the meaningful use appears in these documents. It's been wonderful. It truly is an alignment of the planets, and I hope that we can continue to serve the department's needs in providing advice and collaborative public/private input into the policy ..., so thank you very much.

We, as forecasted last meeting, have a huge agenda today. It starts out with an update from the Meaningful Use Workgroup. We're going to talk about some of the comments that came back from the field and discuss our work plan, and not present the draft recommendations, but we will talk about timing, which is probably the biggest feedback we got from the comments. The PCAST Report is wrapping up, we discussed that last time. They're presenting their final analysis of the PCAST letters and what are its implications to ONC and ONC activities.

I forgot to mention that, first, we're starting out with Peter Lee's discussion of the National Quality Strategy, which is front and center, both the agenda that the secretary's laid out for the country and that we intend to support through our HIT recommendations about policy. Jodi, before lunch, will be talking about the strategic plan update that just came out for ONC. Following lunch we're going to hear from the Privacy and Security Tiger Team with their recommendations. The Information Exchange Workgroup doesn't have recommendations for us to talk about, but it will update us on some of their work. The Enrollment Workgroup does have a letter they'd like us to approve. Finally, we'll conclude with an update from the Certification Adoption Workgroup. So, a huge agenda for us to get through, we'll begin very soon, and we'll close of course, as we always do, with public comments that have been so helpful in our process.

I'll turn it back over to Farzad to lead us through the agenda.

Farzad Mostashari – ONC – National Coordinator
We're going to start with Peter Lee and the discussion of the National Strategy for Quality Improvement in Healthcare. Peter?

Peter Lee – Office of Health Reform, HHS – Director, Delivery System Reform
Farzad, thank you very much. It's a pleasure to join you. I think I have slides that may appear. No, we don't. Okay, well that's fine. First, this committee, I want to note, really serves as a model in many ways for the best public/private partnerships, which is one of the things that we think is critical going ahead in healthcare. I think, Paul, your note of getting David's leadership getting from zero to 60 very quickly was in many ways done because of your leadership and your engagement and the engagement of people across the country. So I really applaud you and what you've been able to do, because the issues around meaningful use that you sort of fleshed through and developed have really been incredibly important.

As Paul noted, since your last meeting there have been a number of things that have happened. I'm going to talk about a couple of them, in particular the release of the National Quality Strategy and also what we just launched yesterday, which was the Partnership for Patients, which really fits in that broad context. I won't be doing slides, but you'll have them and you can refer back to them, which is fine. You also should have a copy of the report itself, which is for a federal report really quite brief at 25 pages. We wrestled with were we coming out with another 800-pound compendium or something briefer, and it really is a pretty brief document.

As background, as many of you know, the Affordable Care Act actually called upon HHS to work with the private sector to develop a National Quality Strategy. For many of us there was a bit of a, "you mean we haven't had one before," and the reality is we had not. The call that went in the Affordable Care Act was driven by a broad coalition of consumer groups, employers, others saying that we need to hold the federal government accountable, but the federal government is not the only engine and cannot be effective without working effectively with the private sector. We need a National Quality Strategy to look at a range of issues so we know where we're going, what the priorities are, and we're all going in the same direction. The Affordable Care Act called on the secretary to engage the private sector in developing a strategy, and over six months HHS facilitated a discussion that I was privileged to co-chair along with Carolyn Clancy from AHRQ and Barry Straube from CMS, that had a huge amount of public comment and engagement in where we should be going. We had comments from over 150 groups on that HHS Website, you can get an 80-page report on some of those comments. Some people around this room commented. It was a rich discussion. We heard some common themes that then came out in what was the National Strategy we released just this last March. The strategy has a pretty simple framework, which is framed around three aims that you'll be pretty familiar with, but then a focus on six priority areas anchored in some principles. So what I'm going to do is walk through those pretty quickly to give us time for some discussion and questions and answers.

First, the three aims. This is a very savvy crowd on many levels, so you'll say well, of course we should have a focus on better care, one of the three aims. Are we delivering what is often framed as the IOM six dimensions of performance in care being delivered to patients? So, delivering better care is the first aim. The second aim, though, is one that as a nation we have not done so well on having on our radar, which is to promote healthy communities, healthy people; a focus on wellness.

Then the third aim is to make care affordable. Importantly, I want to underscore, and this is one of the areas that we got a lot of comments on, is the aim framed in affordability is not an aim of reducing Medicare spend. It's not an aim of saving states' money. The aim is to reduce the cost of quality healthcare for individuals, families, employers, and government, meaning both state and federal. Very importantly, it sets up for all of us an aim that is looking at global costs. It's saying that our aim should not be one of allowing the balloon squeeze of reducing costs in one place so it pops out someplace else. That's a very important marker, because for every one of these aims, and I'll come back to this of how we're using this in the federal government, this is our touchstone. This is how we're going to be framing how we in the federal government look at our goals, how we're moving ahead. These are also, we hope,

and are hearing from many constituents, shared aims with hospitals, with health plans, with consumer groups. So the first three pillars that underlie the framework of those aims of better care, better health, healthy people in communities, and care that's supportable on those broad dimensions.

Actually, let me pause there. Any reactions to those aims? Is that a "Well, of course, duh," or thoughts on what we did there? I'm seeing generally nods, affirmations, again, some of you I know commented on those as they come forward.

The second thing we noted was priority areas. You can't get improvement without focus and you can't have focus without having priorities. We wrestled with this, one of the principles we used is we didn't want to start from scratch. There have been a lot of very good efforts at developing frameworks, priority setting work done by the Institute of Medicine, work done by the National Priorities Partnership, so we very specifically looked at what was out there and used that for comment to get comments back on where we should go, and identified six very specific priorities. They are: First, making care safer; second, ensuring that people and families are engaged as partners in their care; third, promoting effective communication and coordination, and we're hearing themes that Farzad was noting earlier; fourth, promoting the most effective prevention and treatment practices for leading causes of mortality, starting with cardiovascular disease. This is one where we very specifically said there are a lot of conditions of concern, there are a lot of conditions that matter; you need to have focus. We thought it was important to start with the biggest killer, which was cardiovascular disease; fifth, to work with communities to promote wide use of best practices for promoting healthy living; and sixth, to make quality care more affordable for individuals, families, employers, and government by spreading innovation and new delivery models.

Those are the six priority areas that we laid out as the priorities that we're focusing on. Again, when I say "we" this is not a "we" of the federal government. This is a National Quality Strategy that is being followed up on working with the National Priorities Partnership to be a broad coalition on how to carry these out. We also did note two other things in the strategy. The first is, and again, Farzad echoed some of these, there are ten principles we identified. I'm not going to go through all of these. You can read them. Actually, the slides are up there now. So you see on the demonstration here on the left is the aims, the right is the priorities, the bottom is the principles. Three principles, though, that I want to underscore because they actually reflect some of the things that Farzad was noting I think are critically important. A principle to run through all of this is all of our work needs to be anchored in the patients. It should be patient-centered. This cuts across everything we think that should be driving these priorities, these aims.

The second is that while we must have, and need to have, national standards, national standardization, healthcare is local, and being responsive to the local reality of healthcare and being adaptable and flexible to different local circumstance is critically important, so how to balance that having national standards and allowing for local innovation and local activities is critical. The third principle that I'd underscore is the one of alignment, and alignment on a number of levels; one is within and across the federal government. Farzad alluded to the issues of how are meaningful use standards being built into Medicare payment programs development, and they are in a very constructive way. We need to have alignment within the federal government. We also need alignment between the federal government and states. Increasingly, states are facing incredible pressures, need help and support and partnership with the federal government, and it needs to be a partnership, but as importantly, we need alignment with the private sector. None of these priorities will be addressed if we don't have partnerships that are public/private. Those are three principles I'd highlight of the ten we identified.

The last thing I'd note, to then throw it open for some comment, is we identified, and I've gone to the slide, ten policies and infrastructure that are needed as support addressing these priorities. This is one of the areas of rich comments we got when we sent out drafts and thoughts on the National Quality Strategy, was strategy is fine but how are you going to make it happen. The comments we got noted that what are you, either the federal government or states or private payers, doing to change payment to address these priorities? So we identified these ten areas of policies and infrastructure that are the critical drivers of reaching to affecting these priorities.

I want to give a very concrete example of the right out of the gate place where just yesterday we announced the launch of a new initiative called the Partnership for Patients, which is an initiative, which is, again—just like the National Quality Strategy it's not a federalist. It's not a government initiative—it has government as a very active and engaged partner and participant but with the private sector with states. This initiative launched yesterday with the secretary and Don Berwick, but also with, for instance, the CEO of Honeywell represented employers, also with Cecil Williams, the Chair of the Board of the AMA, also with Debra Ness from Campaign for Better Care in the National Partnership. Also with leaders of unions, launched the Partnership for Patients, which said we've identified a national priority around making care safer.

What does that mean to actually move to address that priority? First, we need very specific goals. Working with the range of both experts in the field, stakeholders, we identified two goals too, with the end goal absolutely we want to eliminate harm caused to patients, but let's set a specific goal that in the next three years we want to reduce preventable hospital acquired conditions by 40%, in the next three years. It's not going to be easy to do. We know in many hospitals they've done far more than that in a number of areas, but not in a way that's been spread across the entire country. Second, we want to promote more effective care transitions so people are not readmitted unnecessarily to hospitals with the goal of in three years reducing readmissions by 20%. These are both bold goals. These are not going to be easy to do. The only way we're going to do them is to bring together these policies, these strategies together to change healthcare. I'm going to give you some examples of going down this roster of ten policies and infrastructure that support reaching this goal, why we think this is doable, but also why the role of meaningful use, the role of health information technology is so critical. I'll start at the top on payment.

The Partnership for Payment—excuse me, that shows some of my background of where I come from. The Partnership for Patients is not, is not, I repeat on the record, a payment initiative, what? I'm blushing now. It doesn't have to be because there are some very, very big changes in payment already in the Affordable Care Act around making care safer. For those that aren't familiar with it, in the Affordable Care Act in particular for hospitals there are very, very big deal changes in payment coming down the track. Such that for Medicare by 2015 hospitals will have somewhere in the range of 9% to 10% of their Medicare payment tied to their performance in are they using health information technology meaningfully, a key element, are they making care safer, are they delivering care that's more patient-centered, 9% to 10% of Medicare payments. Now for those that aren't familiar with hospitals' income and expense statement, that is more than the average margin of hospitals in America. That's a big deal. So we're already changing payment in the Affordable Care Act, again, Partnership for Patients is not changing payment.

Public reporting, there are very large public reporting initiatives going on at CMS but also with many private plans having robust efforts to get more information about hospitals, about patient safety into consumers' hands. The Partnership for Patients represents that third lever, a very significant increase in investment of actually close to a billion dollars in supporting quality improvement in technical systems. Half of that is in the form of support for care transitions through specifically designated funds under the Affordable Care Act, $500 million over five years, and $500 million is coming through the Center for Medicare and Medicaid innovation. Which I actually recently moved to from the Office of Health Reform, where I joined as the Deputy Director for Policy and Programs. That $500 million is going to be supporting boots on the ground support to hospitals to implement known technologies that can reduce harm to patients.

Those resources, though, are also going to be supporting better measurement, because a key element right now when you look at patient safety, 95% of the harms to patients are actually invisible. They aren't reported in the standard hospital acquired condition measures that CMS uses, they aren't reported in the standard measures. They're below the surface. So we're investing significantly in better review of what will those measures look like, and then our goal is let's build those into meaningful use, let's build those into health information collected in hospitals so that information is collected as a matter of course.

So this is a key element that we want to be working with you, this committee, as we evolve the meaningful use standards, to make sure in this one area of making care safer we're building in the

information system, the information system supports that will then reinforce all the others. So in every one of the areas there are relevant pieces, but I'd note that the quality strategy is only as good as the policies it rests on, the levers, the concrete changes in health information technology measurement, public reporting, payments that will drive those levers. We're starting down that track very actively in the area of patient care in making care safer, but in each of the other areas, whether it's around cardiovascular disease, around affordability, the innovation ... range of initiatives to make care more affordable. In each of these areas we look forward in the federal government to be working in partnership with the private sector and with others to move down this path.

One other thing I'd note, the national strategy is called on, one, it is a national strategy and we're called on to develop specific goals and measures. When we released the national strategy in March, we didn't do that. We didn't say here are the specific measures for patient safety, here are the specific measures for affordability, because we had such a robust set of comments from the broad community. We wanted to take this year to engage the community, to engage the nation in what are the right measures for cardiovascular disease, what are the right measures for looking at care coordination. That's a process we'll be engaged with, the National Priorities Partnership, the National Quality Forum in the next six months to identify those measures.

The National Quality Strategy identified illustrative measures, potential measures we might use. I think one of the challenges I'd put before this committee is when we look at those measures in many cases elements are I think already built into meaningful use standards and others not so much. So how have you looked at how meaningful use is collected information that reflects care coordination? How have you looked at issues that reflect affordability, etc.? In each of the areas when we think about measurement, I think part of our hope is that meaningful use and the track for better information collection will be an anchor for reflecting how we're doing on these six priorities as well as others. So with that, I would welcome your questions, thoughts, reflections.

Farzad Mostashari – ONC – National Coordinator
Well, just reflections; an equally inspiring talk, Peter. It's just wonderful to see this amount of leadership and vision from the federal government and the inclusiveness in terms of government throughout the country and the private sector. It's a wonderful new age of collaboration, and I think we as a country are up to it. So we'll be glad to work with you on these things. David?

David Lansky – Pacific Business Group on Health – President & CEO
Thanks, Farzad. Thanks, Peter, for the update. There are a lot of places where this strategy intersects with our work in this committee and one of them we're all, even this week wrestling with the stage two meaningful use requirements. Obviously it's a voluntary program. There are a lot of vendors and implementers who feel that it's a very aggressive program and we have to be moderate in what we can expect by 2013 or 2015. Given how much of this depends upon rich information flows you just, as ... described, what else can we do, what can the government do broadly to stimulate participation in the program in a more aggressive flavor that would help generate the kinds of data used described both for patient safety and other applications. We're certainly hearing some of the goals we have for patient engagement and family engagement measures and data are really going to stretch the capacity and the time frame of a lot of the community settings where we're implementing.

So I think we're looking for multiple forms of leverage to try to accelerate this part of the agenda so that the data infrastructure is more than the fragmented separate providers with modest EHR systems in their practice that actually contributes to this community data source.

Peter Lee – Office of Health Reform, HHS – Director, Delivery System Reform
Thanks, David.

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Peter Lee – Office of Health Reform, HHS – Director, Delivery System Reform

We can't comment if we know each other. A couple of things, one, I noted early on my appreciation for this committee's work. Both unto the framing of the meaningful use, but also really is looked at broadly across the federal government as an important source of information and guidance, and I know now in my role at CMS, and we have Tony here, we look at what you're commenting on very closely. I'd encourage you to be commenting on our work, whether it is right now out for public comment, as Farzad noted, the accountable care organization rules. You'll note in those rules significant discussion about the use and relevance and meaningful use attempt to align those issues, and your comments on that are important. I think that the main thing that I think that we can do is promote alignment, and we're doing that aggressively, alignment both across federal programs but also encouraging private sector to align as well.

If you look down the track in the next three to five years the incentives that are federal dollar incentives around meaningful use become very, very big. So having a strong and aggressive and doable set of requirements or standards, we will be putting, we through CMS will be putting a lot of money on the table, which then becomes actual reductions in payments that are very significant for hospitals and meaningful for physicians. Having you continue to push the robust and doable standards is important, but also engaging with private health plans with states to have similar alignment around payments. Right now most of the payment incentives that relate to meaningful use have been federal and most of the private sector have had alignment around other issues, so that's the ....

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Thank you. Peter, this is excellent. I appreciate it. Just a couple of things, as you went through your report, and it may be embedded in there, but that I didn't see called out, and the two terms were appropriateness of care. As we know, the best care and the cheapest care sometimes is no care at all, and again it may be embedded in there, but I thought that was an important point. Then variation obviously being the other issue that. The variation in care seems to be a huge cost driver as well as quality harmer, if that's really a word, so those were the two comments.

Peter Lee – Office of Health Reform, HHS – Director, Delivery System Reform
Those are issues, which certainly, I think, are in the full report when you look at that and issues about affordability, and they marry with the issue of patient centeredness. Getting unnecessary care is not right care at the right time in the right setting, and so both in terms of the principle of patient centered care but also looking at affordability, needed care and only needed care is the key thing we'll be looking at doing payment innovations around and similarly looking at issues of variation. So I think they're good ... and I appreciate them.

Farzad Mostashari – ONC – National Coordinator
Larry? Sorry, Paul, you were first. I have to be trained in my new role here, Paul.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
David Lansky's question prompted a question from me. You spoke to the huge role of quality measures measuring and improving and yet quality measures themselves, the development and the submission for endorsement actually is a voluntary exercise. In meaningful use, we wanted to focus on outcomes and measuring outcomes but probably our biggest limitation was the lack of quality measures in many domains, particularly the ones that are aligned with the clinical data. Is the role for the federal government to cause more of those things to happen because right now it's a voluntary effort? Can you stimulate the development of certain kinds of measurements, measures that fit certain attributes, have certain attributes, and the maintenance, because those are things that end up as cost to those measure development communities?

Peter Lee – Office of Health Reform, HHS – Director, Delivery System Reform
I think there is actually. We are clearly in tight budget times, as we all know, and the Affordable Care Act actually called on the federal government to spend substantial resources ... measures that was authorized but not appropriated. In a number of areas, though, we are looking very closely at how do we sponsor and support the development measures. The initiative we have around Partnership for Patients is an example of where we can't test and assess what we're doing without better measures. So this is a

case where the innovation center is actually investing in, in partnership with our CDC, better measurement, better development of measures to assess what's going on under the surface.

We're looking very closely at other areas as well, though. I think the piece that I would affirm is when you think about outcomes one of the areas I think we had the least robust area in many ways is one of the most important, which is functional status. That's an area that how to both develop that as a piece that we're looking at at CMS and we'll be struggling with resources, but it's a key role that we need to be supporting. I would note that while the endorsement processes are voluntary, as a major payer of care what CMS can do in terms of saying these are the measures that we will be collecting, that we will be looking for, has major ripple effects that we're very conscious of, which is why we put things out for comment, etc.

So again, I'd encourage folks who haven't looked at it to look at, so to speak, the dashboard of measures that are out for public comment in the accountable care organization proposed regulations. We put out a suite of 65 measures and I'll note those measures are aligned not just with meaningful use, but aligned across CMS' programs in terms of how are they consistent with hospital measures in one case and physician quality measures in others, because the model for ACOs is that it's looking at the whole spectrum of care. So that's an area of alignment that we're working on.

Farzad Mostashari – ONC – National Coordinator
Larry?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
Let me join the thoughts on, we seem to have some very strong, consistent themes and it looks like they actually carried through the whole morning here, so this is really a great way to get started. Welcome to your new job with such a great kickoff.

Specifically, one of the things I keep hearing is alignment. I think that that actually is a really key piece. I'd like to add another key word to that, which maybe is parsimony, that just because we put in place a measure doesn't mean we all have to require reporting on that measure. For example, I think it's useful for us to look at what's really the role of HIT and meaningful use and making sure the right infrastructures in place, the right technology is in place so that we can report these measures. But perhaps not require the whole laundry list of measures as part of meaningful use, but really making sure we're enabling so that people can report measures and as measures change over time that we're not bound in with yet another set of regs that need to be updated because they were very specific about the measures. So I think as we go forward we should be looking at building capability rather than this focus perhaps being so much on specific measures.

But having said that, I'm really thrilled that you're including functional status, stepping out of my IT hat into my health hat, because that really is an attempt to formalize what's the person's life like, and that really is an outcome that often gets lost as we look at lab results and weights and heights and all that stuff. If the person wants to get to their kid's softball game, what they need to be able to do that is not their blood pressure measure but their ability to walk or get their wheelchair there or whatever their transportation is. So I think functional status is really a very key thing.

You made the comment about 95% of harm is not reported today, and we often make analogies to aviation. Aviation very much has a culture of safety where there's no risk for reporting problems, no risk for reporting potential problems. That's not the case in healthcare. There's both a cultural belief that we're always doing the right thing, so how can I have screwed up. It really is a huge commitment to doing the right thing and to not screwing up, but when problems do happen the culture is almost blind to them. Then there are specific activities, which encourage that blindness, whether it's liability issues or just the cultural reaction of somebody screwed up rather than the system has a problem. So I think as we work to put in place measurements that are the right measurements we actually have to make sure we're measuring right and that we're not, I think it was actually said yesterday in the kickoff for Partnership for Patients, that we're not just getting improvements in the measures, we're actually getting true improvements.

Farzad Mostashari – ONC – National Coordinator
Thanks, Larry.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
... in those areas.

M
One thing that I'd just echo, I think your note around parsimony, we talk about appropriateness of care, we need to be talking about appropriateness of measurement, ... talking about right care, right time for care, what's the right measure at the right care at the right time. So I appreciate that. Thanks.

Farzad Mostashari – ONC – National Coordinator
We'll do Christine, Neil, and then I'll finish up.

Christine Bechtel – National Partnership for Women & Families – VP
Thanks Paul, no you're Farzad. I heard you say Paul [laughter]. Peter and I had the same lack of coffee this morning. No, but I will say, Farzad, first of all, congratulations. We're really excited to have your leadership in this larger role, and I think you're going to be a victim of your own success so far, because you've set really high expectations based on what you've already accomplished in your former role. I do note the presence of a full necktie, as opposed to a bow tie, and I'm not sure what that means for the new era, but—

Farzad Mostashari – ONC – National Coordinator
... I'm listening.

Christine Bechtel – National Partnership for Women & Families – VP
Okay. I will look forward to a bow tie day. Peter, thank you so much for the leadership that you have brought to HHS and the great group of people that you're working with. You guys have done so much in the last year or so to really bring new visibility to the delivery system reform agenda and it's so needed and so appreciated. My question for you is around healthcare goals. We, I think, have had a lot of discussions in the meaningful use debate around which measures that we choose and how we prioritize them. I think there's a lot of alignment between the priorities that the quality strategy outlines and my hope is if we haven't done it already that we'll crosswalk those to stage one measures and the measures we're thinking about recommending for stage two.

But I think what I'm struggling to see and know the path forward for is really the healthcare goals like cardiovascular disease. I understand getting more feedback and talking with the community about the kinds of measures that we want to use for the existing priorities. But I also think one of the things that we really need in this country is a set of healthcare goals for the next five years or whatever the time period that everybody can really get around—diabetes and smoking cessation and heart disease. The things that really impact our communities and that multiple providers, both primary care and specialists and hospital based providers can really get behind and get excited about. Then we can use meaningful use as a lever to really feed data, and to David's point about voluntary program, get people really excited about participating in this as a way to achieve and contribute towards those goals.

Could you talk a little bit about whether you see HHS doing something to develop those health goals? Because I think we've all struggled in the various boards and bodies that we're part of to say, well, gee, who are we to set health goals for the nation? But that seems like a really important and appropriate role for HHS.

Peter Lee – Office of Health Reform, HHS – Director, Delivery System Reform
A couple of things. There are already a number of goals set out there, I mean, there's Healthy People 2010, and a number of things that are volumes of goals. The challenge I think we have here is back to the note around parsimony, is that for these priorities what are the right four measures for each one, and I think that is something that we're committed to work in partnership with the private sector to this year

identify what those would be. So this is where working with the National Priorities Partnership, working with you, because I think if we don't embed those goals in a way that they can be collected with relative ease they aren't going to be meaningful because we won't have the results.

So this is the next six-month charge that we have working with priority partnership with HHS, with you and others to identify—again, I appreciate that around parsimony, is that we have six priority areas. What is a parsimonious set of measures, some of which may be there already in meaningful use, others of which aren't, and we need to figure out how do we bake those in, is it stage two or stage three? Well, we should be identifying those now.

Farzad Mostashari – ONC – National Coordinator
We're going to have to move on. Let's just have quick comments, Neil and Judy.

Neil Calman – Institute for Family Health – President & Cofounder
This is fantastic work. I have a question about a connection that I have trouble making in my own mind as a practicing physician, and that is that it seems to me that the goals that we're putting forward are goals for the nation around improving the quality of care. Yet what we seem to be focused on, both in the ACO models, where we're looking at attribution algorithms where the people that we're looking at are people who are already in our care, and also in the measurements that we're contemplating around meaningful use, which is very much driven around eligible providers and hospitals looking at the work that they're doing with people who are already engaged in care.

I wonder about how we're going to develop measures or what your thoughts are of how you tie that to the public health goals, where the denominator is really the community. We're working with the most refined denominator of people who are already in our systems. Yet the public health goals really need to figure out a way to connect the work of the providers to what the real public health goals are, which are changing the health of the larger community, including lots of people who are either in disorganized care or not getting care at all, not just preventive care. Which I think is called out here, but people with chronic illnesses who are out in the community and not getting appropriate care. How do we tie those things together?

Peter Lee – Office of Health Reform, HHS – Director, Delivery System Reform
Two things, if I could. First, you reminded me that one of the things I should underscore is while this strategy was called on to address population health, which is an important thing and it's a great thing, to my mind, that we bring together health and wellness with healthcare delivery, I just want to remind folks that there's also going to be a much more fulsome national prevention strategy coming out in the next few months. So that's one piece. But the other is I think that throughout all of our efforts around measurement and assessment, we need to be looking at just that question: are we measuring, when we're looking at community population health, it can't just be for those that have a particular type of coverage. Similarly, when we're looking at diabetics, are we seeing all diabetics or only those that have particular types of coverage? So I think that in many ways is both a goal challenge but also a measurement challenge that we need to have in front of us. We've certainly been thinking about it some and I'd encourage you to join us in that consideration, that's the right question. Judy?

Judy Faulkner – Epic Systems – Founder
Very interesting, thank you. A couple of things, one is as you go through your principles one of the things that I really liked that you said just a few minutes ago was collecting with relative ease. Because as I think of patient safety and quality of care, I think of the time that is available to spend on those patients. I don't know if as you're coming up with what to do in these systems everything that you look at you're also thinking how many extra clicks does it add, how many extra seconds or minutes of time will it take, because I think the balance of that is absolutely critical. The comment I wanted to make is I've been overseas a bit now and going to some of the countries that, at least on paper, seem to have better healthcare statistics and outcomes than we do. What I think is fascinating is that their software systems are stripped of a lot of the regulatory government requirements that we do. So as an EMR or an EHR moves from the U.S. to international use, it has to simplify and remove a lot of things that we collect rather than add to them, and those people still have better outcomes. Part of it, of course, is the disparity of

care and better alignment, but I just wanted to ask you, are you really thinking through the clicks and the seconds added for everything in there?

Peter Lee – Office of Health Reform, HHS – Director, Delivery System Reform
I think this is something that I call on you to think about, and we are absolutely thinking about unintended consequences not just in the form of clicks but you can have unintended consequences in a whole range of ways if you, not just change a measure, but change a payment, etc. When we note that one of the elements of a key infrastructure element is evaluation we need to be making sure what we do is having the intended consequence and what other consequences have and we're being very mindful of. So we take your click comment to heart broadly and so it's not just is it three more clicks, but is it all of a sudden people are teaching you the test and they're not doing other things. There are a lot of ways you can have unintended consequences that I think we need to be mindful of.

Judy Faulkner – Epic Systems – Founder
Yes, I was just using that as an example.

Farzad Mostashari – ONC – National Coordinator
Thank you. I just want to thank Peter. As you can tell, he has been an incredible contributor intellectually and operationally to the work that we do together and it's been very easy and fun to align with him, our work, and will continue to do that in his important new role at the CMS Center for Innovation. Thank you, Peter. Paul?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Before I start with meaningful use, I wanted to catch up on the delinquent task I had of approving the minutes. I was so caught up with the expiration as far as the task that I forgot to approve it. I would entertain a motion to approve the minutes from last meeting.

W
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Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
And second? And any further discussion, corrections. All in favor?

W
Aye.

M
Aye.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Opposed? Abstain, thank you.

Farzad Mostashari – ONC – National Coordinator
Next, we have the Meaningful Use Workgroup with Paul Tang and George Hripcsak.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Good morning, and welcome. I'm going to provide an update on the Meaningful Use Workgroup process, where we are and where we're headed. You can see we've got a lot of alignment with the new federal programs that have been announced and actually I'm thinking of calling a face-to-face meeting with the Meaningful Use Workgroup so that we can catch up and make sure that we go over with another kind of perspective and make sure we're aligned with the new program.

These are the hard working members of the Meaningful Use Workgroup. They've been with us through this entire two years and really attended the calls and had a rich discussion, so I want to thank them.

In today's discussion we're going to talk about where we are with this stage two recommendations, review the HITECH statutory constraints because it plays such a big role in the kinds of things we work on and particularly the timing. We'll go over a high-level summary of the comments we had in response to the RFC, and then focus a lot of our discussion today on the timing feedback that we received. This is for further input as we work through a reconciliation between the drafts that we proposed before and the final recommendations, well, the draft recommendation we'll bring to you next month.

Work plans, as you recall from last year after the release of the final rule for stage one, we had a number of hearings to flesh out some of the things that we didn't have time to spend a lot of time on in the stage one preliminary recommendations. So we heard from specialists, we heard from smaller practices and hospitals, we've dealt with state issues, healthcare disparities considerations, spent a day on patient and family engagement, population and public health, and care coordination, all areas that you recognize fall in the categories of the meaningful use qualifications. We then presented to you some draft thoughts in December, got your feedback, and then issued this RFC, Request for Comment in January. Those were due on February 25th, and then the staff spent a month summarizing those and produced a really wonderful, rich and easy to read summary of those comments. We took that in our April 5th face-to-face meeting and are working through in this April/May time frame in order to put forward to you revised draft recommendations for your consideration and more feedback in the May meeting.

On the 11th, which will happen on May 11th, due to timing constraints we were not able to schedule a second specialist hearing until May 13th, but we want to focus on their needs, which were not fully incorporated in our stage one recommendations. We had some feedback from them. Our final recommendations to you for discussion and approval would be in the June meeting our timeline of getting that recommendation to ONC and CMS by that time. George is going to talk about some of our planning efforts for the May 13th specialist hearing.

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair
Thanks, good morning. It's great to be presenting. This hearing, we realize that we already had a specialist panel but we feel that we haven't sufficiently engaged specialists in meaningful use based on the feedback we've gotten, so we're going to be holding a panel next month. The way I look at it is how can meaningful use benefit specialists, how can EHRs benefit specialists, therefore, engage specialists, and therefore benefit the public the most? So we divided into these first three topics here. First of all, how do we use EHRs to engage specialists in the totality of care that patients get, so care coordination among the specialists, primary care, care management and patients. That's an important part of this. It's not just about the specialists sitting alone, but how do the specialists become part of the whole team facilitated by the EHR and then measured with meaningful use.

The second panel is about individual care. This is more looking at the specialists taking care of one patient. Electronic health records support a specialist in patient care and clinical decision support, that is, how can the EHRs augment the quality of specialty care. The third panel is looking at it from a more global point of view, from a quality point of view, of creating population data perhaps using registries but other mechanisms too, that then provide feedback for the specialty care. Those are our three main specialty panels in that hearing. The fourth one is experience from the field, not limited to specialists, but across the board, pulling in our regional extension centers, perhaps Beacon and Vanguard programs, although we mainly want to hear from people how it's going in the field and not from the first top ... select places, but there's much we can learn from the top also.

So that's our plan for the hearing for May 13th, and our invitations we expect to go out this week, so we're in the midst of planning it.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Great thanks, George. Next I want to cover the HITECH statutory constraints. The timeline for meaningful use, you might think of meaningful use and the adoption of EHRs as a journey, but this journey has very real time constraints. The biggest of course is really the time constraints of reality in the sense of we have a health system that's not delivering the kinds of quality of care that we'd like to have and it's not affordable. So that's probably the biggest timeline. The second timeline is that which is

derived from the statute, the HITECH statute that was back in 2009 and we want to put that in front of you as well because that affects the kinds of things we can ask for and when we can ask for them. First of all, as we're all aware, the Medicare incentives are front-loaded. For the EPs it's 2011 to 2013, for the hospitals it's 2011 through 2013 to get the most amount of payment in the incentives. Those incentives diminish over time.

The other side of the timeline is that there are no further incentives if you're not a meaningful user by 2014, at least under Medicare. The final payments in Medicare are 2016 and for Medicaid it's 2021. The providers will not receive a payment if they do not meet the then current meaningful use criteria, whatever year that is, again, I'm talking about Medicare. If they don't meet stage two, for example, and they're in the stage two area, then they won't receive that payment and the next one will be a lower payment. In Medicaid they can receive full payment as long as they qualify according to the meaningful use stages for six years before 2021.

On the other side is the penalty side. In Medicare if they are not qualified as a meaningful use provider by 2015 they start seeing a decrease in the Medicare payments whether they're a hospital or an eligible provider. Medicaid is different in the sense that there are no penalties on the Medicaid side. The criteria, we think of these as three stages, but the law authorizes the secretary to have more stages than the three, in other words, to have requirement for being a meaningful user beyond 2015. So the bottom line is the incentive policy lever is very much front-loaded from the incentive point of view. The penalty side goes in perpetuity on the Medicare side, however, so there are both sides but a lot of folks are moving in response to the incentive and those incentives are front loaded, and that causes a tension between how much we can ask for and when.

As we know, we had the RFC go out and had 422 organizations submitting comments. Now, each of those organizations, which might be a professional association, gathered input from their members. So this represents a whole lot of input from the public, which is part of the richness of this kind of process. In general, I'm happy to report that the existing objectives are generally supported. There may be questions where in CPOE our draft recommendation was to increase the scope of it, not just be meds but to improve lab and radiology orders, and people agreed with that but said, hey maybe we should do either/or, raise the threshold or increase the scope, those kinds of things. But in general people supported those objectives.

They also took a look at the new objectives that we proposed for stage two and were supportive of those. For example, electronic prescribing for discharge prescriptions in a hospital, not just the EP side, the inclusion of clinical progress notes, the electronic MAR, the patient provider secure messaging, and recording patient preferences for communications, so strong support for these new objectives. For some other new objectives there was some mixed support, not so much that they didn't agree with the objective itself, but there were details and potential unintended consequences that they were concerned about. So for example, advanced directives people agreed with, but how do you ensure, particularly without a fully robust HIE, how do you ensure that the directives that are in your EHR are up to date, that the patient hasn't changed those since then. So those kinds of questions, those kinds of details are things that the workgroup is deliberating.

There are also some concerns already about the objectives, one, around well, the precision of the definition. Now, we put out this RFC talking about concepts, and I wanted to get feedback on the concept of not having a precise definition. Would that cause some ability of not being able to fully comment because the definitions of the objective were not fully defined? Now, the biggest pushback or area of concern that came through in the comments was around the timeline. Again, it's not that people disagreed with the value of the objective, but how quickly can the community get there. We're going to talk about that in detail in just a minute. NIH put forward a request that we include structured family history. You can clearly understand how that impacts health. So we are discussing that as well and talking about where the industry is with its standards and its functionality.

Then we asked a number of specific questions in the RFC and got back answers, some of which are relevant to the Meaningful Use Workgroup and some are good input to other members of the Policy

Committee. One is the strong support for group reporting option, that's not so much within the scope of the Meaningful Use Workgroup, but we wanted to have the public's reaction to that kind of an option. Another option that we gathered input on was whether there should be a testing out kind of approach. In other words, if you're already achieving high performance, should that test you out of some of the meaningful use requirements for EHR use? A third kind of question was incorporating patient reported data. There's a lot of support for that, but we want to be careful to identify the source when it appears before the healthcare professional.

Timing, the big question for today's group as input the Meaningful Use Workgroup as it formulates its final recommendation, not final recommendation but the recommendation to put forward to this group in the next month. There was support demonstrated on both sides. A set of responders said we would like to keep the current timeline because it is so valuable, the things that have been put out there, and the faster the better. There's another group of folks that, again, agreed with the objectives but said it would take longer to do a good job and a safe job in doing that, and some of the groups that were supported both positions are listed there.

The issues, what's the big issue in terms of timing? If there's new development required then from the EHR vendor point of view they're saying well, there's a finite amount of time it takes to specify new functionality, develop it, test it, and get it deployed amongst its customers. That's the time it needs. From the provider side, they need to, one, get that new version of the software, implement it, and train it and get folks to use it. That takes a certain finite amount of time. Things that involve exchange of information, requires a certain amount of things that just take calendar time. So just like nine women don't produce a baby in one month, there's a certain amount of time it takes for folks around the table, the organizations around the table to do exchange, to build a trust in each other, to develop a common set of policies to govern that trust, to put in place the standards and to implement the services. So you can see that all these things take time. It's not a matter of even money that you can speed up that time, it just takes time.

So two scenarios to look at that we used to help guide some of our thinking about timing is, one, for new functionality the final rule and the certification criteria would have to be put in place to start this whole series of events to proceed. The vendor then takes those final criteria, develops its software, the provider has to implement it, the provider then has to report on it currently for one year before they can potentially qualify for the meaningful use incentive program.

The last bullet is if the functionality already exists, and we're talking about already certified EHR modules or products, then we're talking about provider implementation. So the final rule exists, the provider implements those in that organization's EHR, they go through the reporting period, currently it's a year, before they can qualify for the next set of incentives. That's the backdrop to why is timing a big concern.

We came up with some illustrative timing options and would like to entertain any other new thoughts that you have for how to deal with these issues as the comments that we receive. One is to say let's stick with where we are, which is stage two happens as previously intended, which is 2013, and as the rule put out would require a one year reporting period, so that's the status quo. A second option is to keep the same timeline, that is implement it in 2013 as scheduled, but instead of a one year reporting period shorten it to 90 days as it was in stage one. The benefit there from a timing point of view is the provider gets another nine months before the organization has to start collecting data for its qualification. Another option is just to say well let's just move everything back a year, just as an arbitrary time, so instead of 2013 make it 2014. A consequence of that kind of decision would be that providers could get paid in their third year of payment for meeting stage one expectations.

Another option that we wanted to put in front of you for discussion is a phased hybrid approach. One is to say because we talked about those two timing scenarios, for new functionality there's this additional sequential time of the vendor having to develop new software and deploying it, versus the provider just implementing it with a higher threshold. If we could separate those two kinds of qualification criteria and deal with the ones where the providers already have the appropriate software in place and are just meeting a different threshold, that could proceed for potentially in the scheduled time, meaning 2013.

Then delay the stage 2B, the ones that require new EHR functionalities and new certification could be delayed some period of time, for example, a year in this example. So that's an approach to meeting the spirit of meaningful use and the escalator up while providing some relief for the time constraints in development and implementation of this software. Then of course, we're open to any other kinds of options to be discussed. So I'll summarize and then we'll open it up to discussion for timing for your input and ideas.

In general, from the RFC comments from the public there was general support for the objectives that were put forth, both the existing and the new, that they would appreciate more precise definitions and clarification on some of the details, and we're certainly going to be doing that. There was significant concern about the time required for development and implementation and new functionality and the workgroup is going to be working to reconcile the comment that we received and filling out some of the details that were requested for the new requirements. So we'll be presenting the draft recommendations back to you, the full recommendations for stage two in our May 11th meeting for feedback and then present our final recommendations on June 8th.

With that, I'll put up the options that we had come up with so far in front of you so that we can entertain discussion. Tony?

Tony Trenkle – CMS – Director of OESS
Thank you, Paul. Let me also add to the chorus of people congratulating Farzad on his new role. We've been colleagues working together over the past several years with meaningful use and other areas, so congratulations, my friend, and I'm looking forward to continue to work with you.

Two things on timing, Paul, that I wanted to mention, one is this weekend we're bringing up attestation and providers will begin to attest starting this month. One of the things to think about with timing is experience, and I think over the next several months we'll begin to see more of how the experience is really playing out and how that may have some impact on some of the timing decisions.

The second is, I think sometimes we have a tendency to view the universe as being meaningful use centric and as we all know there's a number of other things going on in the world of health IT and healthcare in general that are going to be revolutionary over the next several years. I think it's important, as we look at timing for how we move out on stage two, that we don't forget what some of the other key Affordable Care Act ICD-10 and other major changes to provider work are going on. That that has to be considered as part of whether we look at something as a driver or nice to have and we don't create a disincentive or create additional burdens that are beyond that. So I think that those are two things that we should probably keep in mind.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Thank you, Tony. Deven, and then Judy?

Deven McGraw – Center for Democracy & Technology – Director
I'm piggybacking on Tony's comments a little bit. I'm on the meaningful use group and I'm one of the people that's expressed concern about pulling the trigger too early on timing options before we get a little bit more information about experience. But one thing that did occur to me after some of our discussions this morning that isn't really a delineated option on this list is the one of alignment of incentives. Which might actually cause this to say this particular objective that we thought was so important in stage one isn't as well aligned with some of where the rest of initiatives for the Affordable Care Act are heading. I'd almost move up to number one, consideration of let's have everybody marching in the same direction. Rather than lighting ten fires let's light five fires, and try to have all of the incentives that are aligned, move those that aren't as well aligned, and then think about whether from a timing perspective we need to make some adjustments there based on experience.

M
Deven, can I just comment? Are you saying, should we be looking to eliminate objectives or just not increase those objectives that aren't in the top five?

Deven McGraw – Center for Democracy & Technology – Director
I guess you're right. We started asking people to meet some threshold in stage one and now we're not going to require it at all in stage two. That might not make sense. But I think taking a look at the entire matrix as we have it, cross-walking it to some of the other initiatives that have been put on the table, even more recently than we've begun our work, which we're chasing what's going on a little bit, but that's okay. But I would prefer us to do that and think proactively about how we can align those on the front end.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Judy?

Judy Faulkner – Epic Systems – Founder
Paul .... Some of the vendors have come in and I'd like to pass it along that it's not just the vendor has to develop the software and then the organization has to install the software. But it may very well be that the vendor has a thousand customers who need help with the software and simultaneously doing that across all of those customers at once may be extremely difficult and who do they prioritize and who do they not help. So that is another factor you might want to put into your equation there. There's a piece in the middle.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Connie?

Connie Delaney – University of Minnesota School of Nursing – Dean
Conneie Delaney, I want to, while staying sensitive to the demands both from the healthcare broader systems change and the EHR vendor needs, I would like us to emphasize our continuing listening to the voice of the consumer and purchasers. I was intrigued with particularly your summary on the supportive nature of the comments of the consumers, purchasers, disease management organizations, etc., and found it interesting on the timing issues that with that support we know there is still need for some time in building trust. But when I look at those two factors together, I want to pose a question and a suggestion. The question is that in your perusal of these comments did you see a softening of the timeline because of the consumer, purchaser, etc., support and its effect on trust building, in other words, maybe less time required for that because more than we think is there? Then my comment is that I would tend more in the direction of supporting your option number one of keeping the path steady and moving forward while finding an option for EHR support.

Farzad Mostashari – ONC – National Coordinator
Would you like to address the question, Paul?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I interpreted it as Connie saying let's pay attention to the consumers who are saying let's push on. I think you're saying that consumers may trust this. I think where trust came up was the HIE, the exchange of information amongst other parties. But that's a fair, valid comment in terms of consumers want to push on, because they're a beneficiary.

Farzad Mostashari – ONC – National Coordinator
David and then Paul?

David Lansky – Pacific Business Group on Health – President & CEO
Thank you, Paul. I appreciate the way you and the committee have taken up this issue very thoughtfully and deliberately, and I understand the competing expectations. I have three things that I just wanted to relay to the discussion. One is, to me on the implementation experience side we've all talked about, the real question is what's the risk of non-participation in the program if we stay the course. I don't know how to quantify that or estimate it, but I wish we had some way of putting that piece of data on the table. If it's a we're going to lose 80% of the people we'd like to have in the program, we're going to lose 6% of the people, really changes how aggressively we want to stay the course.

Secondly, particularly I know we'll discuss the PCAST Report shortly, but I think what the PCAST discussion has raised for us all is the realization that there will be continuing innovation in the data platforms and the models we use to capture and transmit data. I'm concerned that we not allow in effect the current engineering and technology platform and the difficulty of making upgrades and revisions and distributing them, as Judy said, to be the gatekeeper of our progress in our national priorities. I don't know how we have a dialogue with the vendors about whether the platforms themselves are not architected in a way which permits the dynamism and the flexibility of the requirements that we want to support, but I think this and the PCAST discussion come together at some point.

Lastly, the two areas in particular where there are new measures in terms of your ... proposal, the potential hybrid, it seems to me that the new functionalities that are implied in the proposal so far really are about care coordination and patient engagement. I don't know how we can, dealing with Peter's presentation, how can we stay the course on the new innovations in payment and health reform unless we make progress on patient engagement and care coordination implementation supports. So I don't see there's really an effective way to keep true to the reform National Quality Strategy agenda and slow down the implementation program.

Farzad Mostashari – ONC – National Coordinator
Let me just make a comment, just the observation that those two comments in juxtaposition speaks to the tension that goes on in the workgroup. Everyone would love to immediately satisfy this and seize how the impending running platform requires this, but then David's first comment was and how do we do it without losing everybody on the elevator or the rising tide. Paul?

Paul Egerman – Software Entrepreneur
It's certainly an interesting challenge that we have here. I wanted to speak to a few of the comments that I just heard. David Lansky made a comment about vendors and their platforms, and in terms of what's involved in deploying changes, I just want to point out it's not just the technology that is a challenge there. If you have a thousand customers, well, the customers have to do things differently if they're going to get a new release. There's training of people. There's workflow. It's not just an issue of can you flip a switch and you've got the new things.

If you think about what's involved in doing something that might seem to be comparatively simple, like going to a new version of Windows or Word, you as an individual user, everybody dreads doing that because it's like resistance to change, you don't just want to change what you're currently doing. Think about what that's like if you're running even a small organization, if you've got a solo practitioner who has a staff of even three or four people, it's disruptive to their practice to change things. It's particularly disruptive, in my opinion, to do what suggested, I think in this slide, to do it every year, to do something in 2013 and to do it again in 2014. That is a hard thing to do from the user perspective, in addition to being hard to do from the vendor perspective.

So that's perhaps a long-winded way of me saying that that solution of 2A and 2B strikes me as particularly difficult and it particularly strikes me that we've got a process that's already very complicated and the attestation is already very complicated to throw in yet another thing I think makes it even harder. I have trouble with the 2A, 2B approach. I think Tony's comment about considering what else is going on in the industry is really important. Two thousand and thirteen has this wonderful target right now of this idea called ICD-10, which I believe is October 1, 2013, and there's a lot of IT organizations that are not really looking forward to that transition, I don't know how best to say that. That ... is a very painful transition, which is also right in the middle of all this process.

My own personal sense of this is I would like if you have this thing that's called other, my sense is that I would be looking at reducing the scope for stage two, so doing something closer to 2A but not having a 2B, doing something closer to 2A. I would also be looking to make it a little bit easier for adoption, so choosing between the first two choices I might be inclined to view the second choice or something in the middle between the first and the second choice so that you have people with just a little bit more runway to get the job done. But certainly reduce the scope. ... you can still increase the thresholds, in other words, you can increase the thresholds for doing things like CPOE, you can increase the usefulness of

existing technology, and you can add a few new things. I'm not saying completely reduce the scope to zero, but that would be my sense.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Let me interject one comment. That curve we had in initial phase, stage one was ... in a structured way, stage two is spread it around. So one of the challenges we have is if we stick with the stage one get data in in a structured way we won't, as David Lansky pointed out, spread it around to the folks who need it whether it's doing ACO, transitions in care, etc. That's one of the things you need to consider as we –

Paul Egerman – Software Entrepreneur
I think you can do some things to spread it around. One of the benefits of some of the information exchange activities is it has less of an impact on the actual treatment process, under the actual workflows, so you can add information exchange transactions to do things like the transition of care, exchange of information. That can be done. Where it gets harder is when you're changing what clinicians have to do in the day to day activity, so I think you can spread it around, maybe not as much, but you can spread it around.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
That's interesting. I'm not sure we've thought about the workflow for each of the proposed measures thinking about the workflow change component. That might be interesting to do that presumed ranking. Marc?

Marc Probst – Intermountain Healthcare – CIO
Just a few comments, they're all around alignment primarily. One was the physician alignment and hospitals and vendors. One is alignment of data, and I was only just thinking of this as we went through it, but ICD-10 itself, I'm not sure what that's going to do a lot of the quality measures. If indeed we're going to go through multiple processes of defining quality measures and ICD-10 comes out we get to go re-do all these measures again and, as people have mentioned, there's a lot of work associated with ICD-10. So it would be nice to see that. There's just a general overall alignment.

I look internally at what we're doing in our own health system and we've got a group working on ICD-10, and a group working on ACO, and a group working on meaningful use, and there's some level of coordination but it isn't great. I have asked a number of times and I don't feel satisfied at this point, of even from an overall government perspective do we understand the coordination of all of these different activities, and where's that picture. I've seen the RI chart for health reform, everyone's probably seen that slide that no one can read unless you blow it up to the size of a wall. But I think there's even more being added. We just saw on quality and safety today some issues, and it would sure be nice to see somewhere where all these things are at least aligned so we can understand what the impact's going to be on the industry overall and us as the end implementers.

Then I think a little bit of the converse of what Judy was saying, it's true the vendors have to pay attention to thousands of organizations when they roll this out. The flip side is we have to receive it from hundreds of vendors and then we have to make sure that those systems work with each other, and that is a huge task. It's way beyond just testing. I think that is a timing issue, so just to throw it in, I would vote for a combination of two and three. Thank you.

Gayle Harrell – Florida – House of Representatives
I'd like to make a comment at some point.

Farzad Mostashari – ONC – National Coordinator
Gayle, go ahead. You're at a disadvantage, so we'll let you cut in line.

Gayle Harrell – Florida – House of Representatives
Thank you so much. Listening on the phone and watching the screen is a little difficult, but we're in the middle of session and there's just no way I could be there, but I have to jump into this conversation. As

many of you know, I have been a long stalwart voice out there saying we are looking to do too much too fast and we want to do things well that we are doing.

I have to agree with Judy, I have to agree with Marc and say that we really have an opportunity in stage two to maybe let people catch up, let's see where this thing is. I would be totally in favor of looking at a combination of two and three, preferably number three, and looking to see that we allow the process to work. I don't know at the state level that we have these HIEs up and running or in the local areas running in order to facilitate the exchange. We don't have the infrastructure in place. I know I hear from our hospitals, I hear from the physician community out there, who are just getting their feet wet in this, and they're just starting into this. They need to get that workflow down. They need to make things happen. We're just not quite ready to start moving ... 2013 into a robust stage two.

I think perhaps the delay in the transition from 1 to 2 says a lot. It would give people the ability to make things happen and evaluate what's happening. I'm a firm believer in let's test things, let's make sure we are where we need to be before we go expanding too much. Perhaps some increase in percentages on things that are already in stage one is fine, but as you've heard me say many, many times we don't want to have this thing fail. We have this one opportunity, let's not set ourselves up for failure and let's look very carefully at what we do in stage two. Thank you.

Farzad Mostashari – ONC – National Coordinator
Actually, before we go to Christine, others on the phone? Okay, Christine.

Christine Bechtel – National Partnership for Women & Families – VP
We had some very good discussions about this in the Meaningful Use Workgroup and I've been thinking a lot about it since that time. It's a challenging issue and it's very complex, and I'm not sure that we fully get even the complexity of it, because as I look at these timing options, there are some missing pieces. I would say that overarching level, I get that we have to balance. What we really need to do here is maintain momentum and forward progress and not just stop for a year, and just keep doing more of the same. That doesn't make sense to me. As David pointed out, it's not helpful for the National Quality Strategy for health reform or for patients, but we also need to understand how to drive broad participation in a voluntary program and not ask for things that are technically not possible, not just hard. Because everybody thinks everything is hard, but things that are actually not possible, we can't ask for that. I get that tension.

What I'm struggling with, though, is there are some missing pieces from this component. The timeline considerations have to be balanced with what the criteria actually are likely to be. So a 90 day reporting period, if there aren't a lot of new criteria, which the workgroup hasn't even made its recommendation, doesn't make sense to me. We talked in the workgroup more about Paul Egerman's suggestion of looking at more of a six month reporting period, for example, but again it really depends on what's in the criteria. 2A and 2B have some appeal and some real drawbacks in complexity, but we don't understand whether in, let's say we did a 2B approach, are those objectives core or menu? Because if they're menu then this is just delaying the stage by a year, and we haven't really acknowledged that I think in these options.

I think two things. One is, we need to understand whether we're willing to just have data capture 2.0, which is what stage one was, or whether we're really trying to get to stage two, which is about information which builds on stage one and gets us closer to stage three outcomes. I would say not only do we need to understand more about experience from the field, which I get that that's not entirely possible yet, but we also need a more in-depth analysis of exactly which criteria that it looks like the workgroup might recommend or part of current EHR systems that are already certified and which are not. We did some great work to do some first steps on that, I know Charlene Underwood is here, she added a lot to the discussion about tweaks to systems and things. I think it's very difficult to consider these without both understanding that at a detailed level, but also understanding menu versus core, advancements in thresholds, all of that placed together, and that's what adds to the complexity here.

I'll say one last thing and then I swear I'll give up the mic. I hear a lot about provider workflow and I absolutely understand change is hard. It requires new workflows when we add new criteria, and I just want to encourage us to always remember when we talk about provider workflow we need to think about patient workflow, because the workflow that we encounter as patients in today's healthcare system is so hard and that we need to balance that along with what's realistic for providers.

Farzad Mostashari – ONC – National Coordinator
Larry and then Tony.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
I'll say something really simple and then something that is new here today. The really simple thing is I really want to encourage this notion of learning from what's working. So we're on the threshold of getting actual feedback of who is signing up, who says that we meet the criteria for stage one. The next few months will actually be really telling in the beginning to get some early feedback and certainly through the summer and into the fall, which this timeline is a huge amount of time but we're right on the verge of getting a fair amount of feedback of who's actually attesting that they're there.

The second piece is life doesn't end with stage two, there's stage three. I really don't want to be having this discussion in two years. So my suggestion would be that we actually start looking at stage three now and start to frame what we're doing for stage two in terms of where we want to be for stage three, because otherwise we're going to be in the same no time in another two years. We really need to accelerate our whole model and so maybe the crunch around stage two is the right place to crunch so we can start to really build a real stage three and maybe go back to that core concept. That stage one is about getting data, stage two is about sharing data, and that we really looked at, rather than messing a lot with what's in stage one as we go to stage two, that we focus on getting the exchange piece started, recognizing that there are still huge conceptual hurdles to getting that document flow working well. When you get that care summary, what do you do with it? That's a new thing we didn't used to have. How does that play into the whole thinking? So we've got some big conceptual hurdles in front of us to start to do exchange, plus, let's not time crunch ourselves on stage three. Thanks.

Farzad Mostashari – ONC – National Coordinator
Tony, and then David Bates.

Tony Trenkle – CMS – Director of OESS
A few minutes ago I mentioned the point about harmonization with other initiatives and not just harmonization one of the other points I want to make is that there are multiple levers for achieving what we want to achieve ... improving the healthcare system. The Affordable Care Act gives us a number of levers as well as what we had with HITECH. I think it's critical that we look not only with stage two and stage three, but what are all the activities that are occurring and what are the goals, whether it's the National Quality Strategy or other types of improvements. What are the best levers for achieving them and what is the timing for achieving these various improvements. Because I'm concerned if we look at meaningful use as the center of the universe and don't think about how these other levers can maybe accelerate change or combined with meaningful use accelerate change, I think we're missing an opportunity. We could tend to then load down meaningful use in future stages without looking at maybe there's some other ways of achieving the same outcomes, maybe faster, maybe better.

Farzad Mostashari – ONC – National Coordinator
David Bates?

David Bates – Brigham and Women's Hospital – Chief, Div. Internal Medicine
Thank you. I agree with the point about learning from experience that Tony and Larry made. My concern is how fast we're going to get to where we want to go. My own belief is that while stage one will have been a good thing, that really will not result in very much change. I think we have the potential to start seeing some improvement with stage two, although I'm concerned about whether there will be very much with that and if we slow things down too much we really could lose some ground. I think that it's going to be important to have some more decision support in stage two. We really gave providers a free pass on

that in stage one. I also think that if we want to begin to address some of the issues like transitions and preventable harm in hospitals, we won't be able to afford to back off too far. If we do, hospitals just won't have the tools that they need to make those changes. I personally like two and 4A. I think two just gives providers some additional flexibility. I clearly see both sides of this and I'm sympathetic to people who are struggling, but I think 4A is one approach to dealing with that.

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair
Let me just comment on, there's been a theme here today of focus. Remember, there are two orthogonal decisions on timing. One is, there's a balance between focus but move more quickly, or try to do more but you have to go a little more slowly. And that question we could talk about now and maybe even answer now, which is different from experience, which shifts the whole thing. Whichever one of those two we pick might shift it forward or back. What I'm generally hearing hear from Tony, because he's pointing out there's other ways to do this besides meaningful use, that is in fact doing it twice may be more harm than good in some ways because it gets confusing and they could potentially conflict. But whether people wanted to go faster or slower, everyone seemed to say that stronger focus was important and not a potpourri of things that would be nice to do. Then we still need the experience to say even if we focus then how quickly do we go within that context.

Farzad Mostashari – ONC – National Coordinator
Thank you. I had a couple of questions, the first for George and Paul. The first is, this concept of momentum, I think people have used it among us two different ways. One has been momentum and participation, that we need to keep momentum, we need to keep having increasing numbers of providers participating in the program. We've also heard the term momentum used in terms of momentum in terms of the functionality and what people are actually doing and how they're using the system and keeping momentum up the escalator. In designing what we're talking about stage two, if you recall, we had an overall escalator but there's also individual escalators in the proposed what we put out in the final rule that said that for an individual eligible professional, eligible hospital they have their own escalator within the larger escalator. So the first year they're in the program they're in Stage1, whatever stage one happens to be at that time.

So in your discussions with the Meaningful Use Workgroup, in essence we're talking about what is stage two for the people who have already been in the program for a couple of years. But there's also the question of what is the entrance criteria for the people who are just now entering, the other momentum concept of the people who want to join the program what is the threshold to entry and then where do you go to keep people on the escalator? So has there been discussion, what I'm seeing here is really a mix of those two concepts when we're talking about stage two, assuming that everyone on the first time to go goes right to this higher bar, but in fact there are individual escalators, aren't there?

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair
There haven't been a lot of discussions, but that's a very good point. The one thing that's been stopping us is stage three if it's for everybody in 2015 you then hit this wall and you may be starting slowly on your escalator but then there's a wall in the middle of your escalator you need to jump up or not. Now, if you do it any other way there's a problem because for many organizations 2015 brings them penalties, which are much bigger than the incentives, so you don't want to create a perverse incentive not to adopt just because that will give you extra time, will delay your penalty phase. If you let people go in in phase one in 2015 and then in effect they avoid penalties by slowing their adoption. So it's tough, and I'm guessing that's why CMS went the route that they did with the final rule. So that's the one caveat about what you said that is making us look at it a little bit the other way. Tony, do you have any comments about that?

Tony Trenkle – CMS – Director of OESS
No, I think that's one point, George. The other point I was going to make too is we have the disconnect between the Medicare and Medicaid providers which also is going to be a consideration when you think about how many different ladders you're going to have for people to climb.

Farzad Mostashari – ONC – National Coordinator

I think the analogy to the escalator is the later you get in, the faster the escalator is running. That does have implications, and Paul Egerman mentioned that every year kind of a change, because if you do enter in 2012 then you may have to get on ... pretty quickly on an annual basis, so that's a point. I mentioned a couple of other points in response to folks, just sort of a reality check. The notion of exchanging information and particularly addressing the health reform needs of care coordination, that's unfortunately new functionality for virtually every EHR, and something was mentioned, well, why don't we check what's in there now. Unfortunately, the things that we really need are not there in the current system, so that is a big threshold to cross from the vendor side and the adoption side.

The other point I thought was very interesting was, and we heard so much about it this morning, is all these other programs that not only have the spirit of meaningful use in it, but it has the words meaningful use in it and type. So we can flip that, and I think that's where Tony was going, we thought of ourselves as, boy, we're really compressed because you only get $1,000 at the end, but actually if the reform continues and payment changes are made the financial incentives can continue beyond the 2012 and 2013 that we thought we were under compression. But it doesn't help us with the, well, how fast do you have to get there anyway. So the internal, external escalator is how fast the escalator's going. It's how much is being loaded on to this escalator, as Tony mentioned, but the real burning platform is we don't have a system delivering what we need and we're out of money. So that's a different thing. We almost have to get there.

The other question I have for the group, and maybe Charles in particular, is what we hear from hospitals and hospital CIOs, for example, is, as Tony said, this isn't the only thing going on and there are some things that I have to do so that my hospital can get paid. Those are at the top of my list. Then we have to make a decision. Do we focus on meaningful use or do we focus on ACO strategy, for example? One way to think about this question is, and similarly on the private plan side, what are the things that, for example, hospitals or providers need, what are the information tools they need to succeed and thrive in that system? So what are the things, you mentioned ... but are we putting things into—and I think gets to the focus issue and what Deven was saying. Are we focusing meaningful use, or would it be appropriate to focus meaningful use to be the tools and behaviors you need to succeed in any system that's going to reward more coordinated, higher quality, safer care?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
That's been always our driver and we're just meeting up with the reality of it isn't there, it's new, and it takes a lot of time of the balances, and we don't want to lose everybody. The other point is, to your comment about watching out for the little guy, the experience we're going to get in the next couple of months is not coming from the little guys I don't think. They're coming from the folks that already were there, and so that's where we're in a difficult situation of having to act before we have data that we would like to have in order to inform the opinion. Charles?

Charles Kennedy – WellPoint – VP for Health IT
I think what I'm seeing, and many of us in the health plan industry are seeing, is in getting ready for an ACO world the thing that jumps out is the biggest gap is of course health information exchange. Not just health information exchange as we're describing it, but health information exchange where there are discrete data elements and some level of semantic interoperability, but some level of bringing the information over so that the meaning is maintained. You're seeing health plans, Aetna and United, invest many hundreds of millions of dollars in acquiring health information exchanges, but they too are running into this issue of what comes out the other end isn't necessarily usable for care coordination purposes. I think to what Paul's saying, some of the technical needs we really do have a fundamental challenge around getting the pros and the HL-7 data stream into a form that you can use for care coordination, care management, and disease management and all the rest. That's just fundamental.

Farzad Mostashari – ONC – National Coordinator
Neil?

Neil Calman – Institute for Family Health – President & Cofounder

My opinion is that the ACO movement's going to eat meaningful use for lunch. I think the meaningful use thing is time limited, dollar limited, the ACOs are complete unknowns. If even one-tenth of the people who say they're going to become ACOs become ACOs, and if even one-tenth of the number of people end up in them, that the people who say they're going to be ACOs claim will end up in their ACOs, it's going to become a dominant force. I totally agree with you, Charles, that the issue, I wouldn't say health information exchange, I would say care coordination because I think you can exchange all this stuff and it can be pretty meaningless unless we actually think about what the information is that needs to be exchanged and how it needs to be exchanged.

And so some of the things we're thinking about now, it's not just enough to know what somebody's labs or x-rays are, but what we really need to know as we talk to each other are what are our plans with the patients? Where are we heading with the patient? And when somebody calls me from the hospital and says I have your patient in the hospital, the first question is what were their last labs and their EKG, but the second question is, so what were you planning to do with this patient, and that information we don't really have captured or exchanged.

I think the idea that you're talking about, Paul, about sort of framing, looking at the ACO need and using that, maybe just stepping aside from where we are right at the moment. Step aside for one meeting and using that to frame the discussion that says if we hadn't been talking about meaningful use like this so far and what we're really talking about is that coordinated, integrated system of care that improves quality and reduces cost. How would we have started this process, and then see where those things combine and if that doesn't change a little bit change our focus in some of these areas. Again, I would go back to my previous comment, that I think it drives you to look at populations more and start thinking about managing populations. We're pretty far from that in the way that we've been thinking about this provider focused kind of vision of healthcare. So it would be a good exercise and I think it reflects what the conversation is right now in the healthcare community.

Farzad Mostashari – ONC – Deputy National Coordinator for Programs & Policy
For those of you on the phone, there's a lot of nods and smiles, including from what seemed to be people representing two different viewpoints on the timing issue. I would say the other thing that has come up in the context of the ACO is around population health management. What are the tools needed to reach out to do the communication with patients, and that's in addition to structured data moving from hospital to doctor and doctor to doctor there's also the patient's part. Which again, as Paul said, a lot of this has been implicitly in our minds as we planned for and we discussed what should be in meaningful use, but being able to talk about it explicitly to providers and hospitals. That meaningful use is a way for you to get a jump start on what you're going to need to do to be successful in an ACO, for example, is very compelling.

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Farzad, I'd just ask the group, so one tool we have in our focused toolbox is trust in our technology and early decisions. That is, we have a tendency to say we're at threshold X, we have to go to X plus something else. Another way to say it is if we got it into the certification and if people are using it at 30% there are two possibilities: it's a stupid idea, or it's a great idea. If it's a great idea they're going 100%, and if it's a stupid idea it might stay at 30%. If we want to focus, one way is not to dial up every threshold but just trust that that will work and try to get them up through other ways. In fact, in the update for the problem list and the medication list what we tried to do in our proposed stage two is not to come up with some wacky scheme to make sure it's up to date, but say here are other objectives that would drive that anyway. But people in the workgroup would have to be a little comfortable with the idea of trusting the technology and saying okay, we're going to leave the threshold here. That's not where we want people. But we've got it in certification and we know we're at least trying it and let's focus on the ACO-like objectives.

Farzad Mostashari – ONC – National Coordinator
David Lansky?

David Lansky – Pacific Business Group on Health – President & CEO

... George's, that in any of these areas the industry adopts the capability and then the whole industry adopts it and moves on, think about the evolution of word processors and other platforms. And maybe our job is not to focus on dialing up or down the thresholds within a capability, but to turn the spotlight on the next critical requirement and if anything, turn down the lights on the old stuff so that we aren't sending too much signal. So to me it's like signal response and now it's time for a new signal that will trigger a new response. But it has to be very focused, laser-like, discrete, and high value to all the participants. Neil's arguing, and I think rightly, that maybe ACOs or whatever comes next, episode payments or something else, are likely to be high value from a business point of view to the provider community, and at least at the moment that appears to be the case.

We should in effect marry the National Quality Strategy values with the next high value business requirement and turn our spotlight on the specific capabilities that we think will achieve the goals we've all talked about today and other times. To me then maybe stage two, if we take this idea of information sharing or connectivity, or care coordination, patient engagement, there are a couple of very discrete core capabilities we really need to have achieved to support a lot of our goals. And perhaps we should take our matrix and skinny it down and focus on what's the critical leverage add that we want to see achieved. How do we express that in a way most likely to get that 30% or whatever numbers George speculated which signals to the market to go down that path without us trying to micro manage that.

Farzad Mostashari – ONC – National Coordinator
Christine and then Charles, and then we'll go to the phones.

Christine Bechtel – National Partnership for Women & Families – VP
I like the idea in theory. I think I have two questions of one concern and one question really about operationalizing and what that would look like. I think that's a good idea to look at David's side of the critical leverage points and make sure that we are doing the right thing. But what if the ACOs, what if we don't get it right? What if they become the next HMOs? What if we have a Helen Hunt moment? We don't know what these things are. So my challenge in operationalizing this concept, which, again, I like very much, let's take one of my favorite criteria, the view and download, giving patients access to their own health information in a way that they can download and take with them, are ACOs going to pay for that, incentivize that? I don't know. I think on a lot of the quality safety efficiency disparities criteria, yes, that's probably a safe assumption. But on the patient engagement criteria, we don't know.

So the threshold idea actually becomes very necessary because in certain instances, with particular criteria like this, we have no guarantee that the payment system is actually going to reward this, because for most ACOs it's going to be on top of fee-for-service. So we still are going to have competing incentives out there. While I love the idea in theory, in reality I think there are probably, as Deven said, there are some things that we can do to be more parsimonious, but there are some areas where we can't make some of these assumptions and we need to be pretty careful.

Tony Trenkle – CMS – Director of OESS
... tend to agree with that, because I think, once again, meaningful use is not the center of the universe. We can write rules for ACOs. We can test things through the innovation center and do other things that focus on the patient getting information, other types of areas that we've been looking for meaningful use as the sole way to do that. It's the same as what we're doing with meaningful use, it has to be done through rule making. So I don't see why you can't look across and say well if this is not in the ACO rule what do we need to do to create something in the ACO rule, either this one or future rule making, that begins to bring some of the patient information and other things that you're looking for.

Christine Bechtel – National Partnership for Women & Families – VP
I think it's a great idea, Tony. I think it's real easy for you as the agency to say, right, so for me as a patient and consumer group I don't have a guarantee that you'll do that in my leverage point and our jurisdiction is meaningful use.

Tony Trenkle – CMS – Director of OESS

I understand that. I'm not disagreeing with you. ... rulemaking, but if the concept is put out there I think in a lot of cases people aren't looking at that as part of the concept of what might be a criteria for an ACO. Just the same with meaningful use, we created a lot of the concepts within meaningful use that weren't there initially when we first started looking at it. So I think we just have to adopt a more global mindset as to what are, as I said before, what are the best levers and what are some other alternative levers besides just using meaningful use—

Christine Bechtel – National Partnership for Women & Families – VP
And probably also what are the populations that are affected, because the universe of providers participating in ACOs is not the same as meaningful use necessarily or some of the other initiatives, so I think broad reach is good.

Tony Trenkle – CMS – Director of OESS
Right.

Farzad Mostashari – ONC – National Coordinator
Charles?

Charles Kennedy – WellPoint – VP for Health IT
I want to pick up on something David Lansky said, which is that this emphasis on ACO potentially could be a signal to the industry. To give you one concrete example, for years health plans have tried to work with the pharmaceutical industry to get their pricing to be not just what the market will bear, so to speak, but more associated with value, outcomes based benefit designs, outcomes based formularies, those types of things. And they haven't really taken off, and part of the reason is that there wasn't a way to get that information consumed by the physician so that those formularies got operationalized within the physician's environment. We started working with AstraZeneca, who's one of the first pharmaceutical firms who stepped up and said, look, I'm willing to have my pricing be more aligned with the value that my pharmaceutical agent creates. But the key to that was the anticipation of the ACO and the anticipation of health IT being a highway to bring those clinical decision support aids within the clinical environment. So I just want to emphasize I think that the signal to the industry might give you a path to transform healthcare, so to speak, much greater than just technology in and of itself.

Farzad Mostashari – ONC – National Coordinator
Before we go to Larry I just want to point out, the ACO rule is the first out of the gate. There are going to be a number of innovations in payment that are going to come out of the Center for Innovation that are in the legislation around value-based purchasing, around shared savings, around bundled payments, around episode groupings, that by ACO I think we're using that as shorthand for payment that rewards quality and coordination. There are going to be a number of those coming out of Medicare, but also a number of those being now supported in terms of what's happening in the private, which is so critically important.

But one of the things that we need is to not only be thinking about and supporting what Medicare can do on the payment side, but also, as the secretary said yesterday, for far too long Medicare has been a drag on the ability of the rest of the industry to innovate, and we're not a drag anymore. But now that means the rest of the industry has to step up too and we can work together on these issues. I think, Charles, you helping bring in the perspective from the plan so that what we come up with is going to be strongly supported and rolled into what providers need to be successful, not only for Medicare payments. We heard about the 10% there the hospitals are going to be at risk, but also on the other contract, because this gets to the non-covered folks, the folks who are non-eligible providers, they're not going to be helped unless provider plans see this framework as being on their critical path. Larry?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
I hate to derail this great discussion on ACO with what feels like a complete techy comment here, but I can't resist and I think it's important, and that's standards. One of the things that I think there was a lot of feedback from on the initial meaningful use rules is that the standards are not standard and that if we really want interoperable data that doesn't cost a fortune in health information exchanges now to

transform that data, that we need to get standardized data. And the sooner we get it the more important that is because there's a really long runway to going from the data everybody's been using in their systems to standards that are actually built into the ... locations, and that is a huge and complex journey as you start to move your vocabularies. I really want to put in a note that as we move forward with stage two that we really revisit standards and strengthen our recommendation that a standard means one. And if we can't agree on one we should have none until we agree on one.

Farzad Mostashari – ONC – National Coordinator
Thank you. This has been a terrific, terrific discussion, ranging far from but I think in the right way as this Policy Committee often does, elevating an issue up from do we choose option 4A to what we're really about. Thank you all so much.

M
I just wanted to thank the committee as well. It's been a fabulous discussion. It's brought new ideas into the workgroup and we'll be richer for it. Thank you.

Farzad Mostashari – ONC – National Coordinator
Next up, and we're right on time again, we have the PCAST Report Workgroup, the results of their analysis, with Paul Egerman and Bill Stead.

Paul Egerman – Software Entrepreneur
Thanks, good morning, I'm Paul Egerman and Bill Stead and I are going to give you a brief overview of the report from the PCAST Report Workgroup. The PCAST Report Workgroup actually completed its work, and you have the letter in front of you that we're going to be asking you to accept so we can send to the national coordinator. The PCAST Report, to very quickly refresh everybody's memory, the PCAST, the President's Council of Advisors on Science and Technology, it's an advisory committee, much like this committee, and it issued a report December 8, 2010 that was indeed read by President Obama, who besides PCAST had his advisors advise him, and they accepted the recommendations in that report. So what we had as a workgroup charge is this charge here, which is to assist ONC in synthesizing and analyzing the public feedback to the report, discuss the implications of the report on ONC's strategies, assess the impact on ONC's programs, evaluate the recommendations in terms of their impact on the ONC strategic framework.

So if you look at this workgroup charge you see these words "assist," "discuss," "analyze," "elaborate." What you don't see is the word "judge." Our charge was not to judge the report in any way, and so basically it's very important that the comments in our letter and the comments we make today shouldn't be interpreted as either endorsing or rejecting the technology or endorsing or rejecting any policies that might be inferred from the PCAST Report. We simply did exactly what was in the workgroup charge and so we have this document in front of you, it's 45 pages long, and it includes our evaluation. It does not include any actual specific recommendations. In fact, it's a series of alternatives for ONC to consider as they proceed with the architecture. This is a list of the workgroup members. We were fortunate to have a terrific group of people who had a range of opinions on a number of the topics involved in the discussion, but we did get consensus on the letter. Indeed, the letter was written almost every member of the workgroup contributed to writing the letter, so pretty much every member of the workgroup wrote one portion or a section of the letter.

We also were fortunate that we got a lot of support from ONC, so we listed the ONC people who participated in this process, and in particular Doug Fridsma, Jodi Daniel, Jamie Skipper, and of course Judy Sparrow was particularly helpful. Judy is always extremely helpful, but we pressed her pretty hard because we were ... a crazy schedule, meeting almost every two weeks for three months. We also got continuing feedback from the members of PCAST, Christine Cassel, Craig Mundie, and Bill Press. Bill Stead and I briefed them on Friday evening on this letter also. We're very fortunate to have this group of people. Quickly also, this is information that I did present before but I think it's important to frame the discussion.

As we read the PCAST Report, there were three fundamental directions that were important to understand about the report. The first one is, it says accelerate progress. The report has this very strong call to action in it, to act aggressively and to act boldly, so there's clearly a call to action there. The second concept here you see underlined the expression "new exchange architecture." We think it's very important to understand the PCAST Report is not just a high level ... report that says information exchange is good. It is a report that's advocating for a specific exchange architecture, which has a mouthful of words, but it's really two concepts. One is the universal exchange language. The second is an interlink search capability. But the main concept here is this is a specific architectural concept. It does represent a change from ONC's concept of what a thousand flowers bloom, so this is like a flower pot, I guess, but there's a bit more of a focus. The third thing that it's also very important to clarify here is this is an evolutionary process. This is not rip and replace. This does not mean that some of these things are going to be radically different, so this is not a 90 degree turn for ONC.

In our report, we did our best to try to describe some information about describing how the new exchange architecture works. There was a reason why we called it the "new exchange architecture" instead of the "PCAST architecture," and we'll get to that in a minute. But as part of the description we also said this is not a complete description of everything in health information exchange. It was interesting, Charles' comment in the earlier discussion about semantic interoperability, but that doesn't necessarily solve every problem. So the concept of this new exchange architecture is if you think of all the healthcare information exchanges like a whole series of building blocks and tools, this new exchange architecture is one kit of tools that does one series of functions but doesn't necessarily do everything. So it does not do, for example, a lot of the push transactions. So you don't get things like that, the X12 transactions, the claim form transactions really aren't contemplated by this architecture, or ePrescribing, those kinds of transactions are at least not immediately impacted by this entire approach.

So we did put some effort into explaining what the new exchange architecture is all about. We tried to explain it from a perspective of what it looked to users using this system. We also did a technical description, so if you fancy diagrams there's a complete description in the letter from a technical standpoint of how the entire process works. We also spent a fair amount of time on feedback from the public. We're not going into that on today's discussion, maybe because we discussed that a little bit in the last meeting, but the public feedback significantly impacted all of our work in terms of understanding the architecture itself and the concluding comments that Bill Stead will be talking about.

As part of our work, what we do is we divide ourselves into two taskforces. One taskforce dealt with some of the policy issues. The other taskforce dealt with some of the implementation of the technology issues. On the policy side what we tried to do was to do a process that we called "policy spotting." We spotted the policy issues without trying to resolve those issues, which is actually a great thing to be able to do. To figure out how to solve these things is very tricky, but to be able to say here's a problem, for a challenge that's a lot easier to do. These are actually terrific discussions and I think it indicates that we have a lot of terrific discussions ahead of us in this Policy Committee.

In the letter, we tried to highlight the top three policy issues. The first one of course is privacy and security in any situation involving information exchange or data liquidity you would expect that to be the case. So there is some interesting discussions about that. The second we had trouble doing the title, it's called "Multi-Patient, Multi-Entity Analysis," which is also what sometimes people refer to as secondary uses of data, so I guess there's something interesting that secondary uses ended up being number two on the list. But basically there was some very interesting discussions here also about the idea that you have information exchange data structure that's being used for multiple purposes, and what are the policy impacts, what does that mean in terms of various policy issues.

The third of course relates to governance, which Farzad talked a little bit about earlier, but there's lots of governance issues about how this exchange architecture will work. You've got these entities that are called "record locator services," or DEAS. I understand people are starting to pronounce that. There are two pronunciations, but apparently "DEES" is the one that's winning right now. But there's significant governance issues about are these trusted intermediaries, how is all of that going to work. So we highlighted those as the top three. In the appendix, though, there's at least another dozen other topics,

issues relating to malpractice, issues relating to how does HIPAA relate to the metadata, there's a lot of very interesting net policy issues. We learned that the policy issues are all interrelated with each other, and clearly they're related to the technology issues. I think Bill now is going to take us through how we handle the technology side.

William Stead – Vanderbilt – Chief Strategy and Information Officer
Thank you, Paul. As Paul said, the PCAST Report included directional statements, but it did not actually provide a specific recommendation about a technical implementation. So one of the things we had to do was to identify alternative technical implementations, and we did that by starting to define the four use cases. The first was a simple push by the patient between two points, and in essence, uses existing theme PHR and portal implementations as they're available in the market today, existing policies, existing standards, but wraps the data in a UEL envelope and begins to include some privacy and provenance metadata so that applications can take advantage of those. Simple search takes, for example, helps a clinician who already knows, who has seen the patient, allows them to actually locate where that information is, and obtain it. Then the third is a complex search that, as best we can tell, would support the end game of the PCAST Report. The fourth dealt with how you could retrieve de-identified data where the patient's privacy tags had indicated that it would be acceptable to reuse it for research purposes.

We, based on those use cases, present a table that presents these three implementation approaches side by side. One of the ahas that we had as first a taskforce and then I think as a working group is that the three alternatives were not choices we had to make. They actually were a progression and that you could start with the first and progress to the second and third as the different combinations of policy and technology tested out through pilots or test beds. So I think we found that to be a liberating idea. You'll see that we identified at high level 15 components of both technology and policy that would have to work together to make one of these approaches work. The second realization we had was that you really needed to think holistically about those 15 components, so as you made decisions about one they affected the others. So although it is progressive, you really do need each point to have a holistic view of how the pieces might in fact fit together.

We looked at alternatives that we felt could be dealt with within the timeline of certification and meaningful use for stage two, the difficult challenges that you were just talking about. One thing that seems possible would be to do the standard definition around just the minimal UEL that would allow EHRs to be certified as being able to publish or expose information in that UEL for the purposes of this, if you will, push patient approach between two points. That seems achievable because one of the ideas in PCAST is this decoupling of syntax from semantics. Where you are then actually able to use version controls and naming authorities to let them evolve so that you don't end up having to get it right the first time, you're actually able to get it in the right direction and then it can evolve and extend. The second alternative that seemed reasonable in that same time period would be to sit on top of that same definition of the UEL metadata criteria for other pieces of, if you will, the meaningful use menu.

We looked at trying to see whether there are any of the things that were currently being discussed by the Meaningful Use Workgroup would be, if you moved in that direction we would regret it later, and we could not see any problems in regard to PCAST with the things that were currently being considered by the Meaningful Use Workgroup. The things that were currently being considered all seemed to build upon existing things that are fairly well developed or the current kind of push technologies. So that we think you could proceed with those with PCAST, if you will, maybe coming along and taking some pressure off how we get to stage three, may be another way of thinking about it. We did identify certain pieces of the ongoing work that are clearly going to be important no matter what we do. PCAST reemphasizes their importance, if you will, things around identity matching, obviously the controlled vocabulary efforts, etc., so that work needs to proceed at full pace.

At the end we made three summary statements. As Paul described, the workgroup brought many different perspectives to the table. As we say in the report, there were some that liked aspects and there were others that disliked aspects. But I think everybody agreed to these three statements and everybody had a chance to micro-edit these three statements. So there is no question that PCAST provides a

compelling vision for part of what we need, and there's equally no question that there are major policy and operational feasibility concerns that need to be worked out if that vision is going to, in fact, be .... Therefore, we believe that aggressive, rapid progress is possible, but only if it's done with an eye to this incremental progressive implementation that the table outlines and in the context of large scale test beds that let us actually know what works and does not work from an integrated policy and technology perspective at scale. Thank you.

Paul Egerman – Software Entrepreneur
It's interesting, you look at this discussion and a final sense as we try to write in the letter, that basically ONC has to achieve this balance. There's a balance between, on the one hand you've got this PCAST Report that has this inspirational picture of how information exchange can happen and so very much of a can-do attitude, so you've got that inspirational vision on one side and on the other side you have some pragmatic realities of an EHR system. So the challenge that we had was to take this inspirational report and translate it into the reality of stage two and stage three, which is sort of like what are you going to do next year, what are you going to do now. And in some sense it's also a lot of the challenge that we had in the previous discussion about meaningful use, where we have a lot of things we really want to do but there's also just some pragmatic realities about what can really be done and in what sequence. This is our summary. It's a clear statement about this concept of incremental test bed approaches. The whole purpose of the use cases that Bill presented was to show that that is doable, possible to do, so you could do it on an incremental basis and resolve some of these issues.

We'd be happy to take questions. We're hoping that you will accept our report, because we understand the formality is we cannot send the report to the national coordinator unless you accept it.

Farzad Mostashari – ONC – National Coordinator
I just want to thank Paul and Bill and all the members of the PCAST Workgroup. You really met the charge that we put to you. It was a difficult charge. There were lots of ways you could have gone down rabbit holes and never come out. I think it's a real credit to the workgroup as a whole and also to you two in particular as chair and co-chair for meeting the mission and the mandate and the charter of that workgroup to provide us with options for implementation moving forward on the vision within a very compressed time frame. I want to give you my personal thanks for a job very well done. Thank you. Comments and questions? Judy?

Judy Faulkner – Epic Systems – Founder
I'm a little confused. Can you explain, what is the recommendation?

Paul Egerman – Software Entrepreneur
There is no recommendation. It's hard to disagree with a recommendation because I guess the comment Larry said is sometimes the best care is no care. There's no recommendation here. What there is, is these statements of possibilities, that you could have these incremental test beds, that there's an explanation of what the report does and there are a number of alternatives. There's a whole interesting discussion of top-down, bottom-up, middle-out, but those are alternative ways in which ONC can approach implementation of the PCAST Report and some discussion of pros and cons of doing that.

William Stead – Vanderbilt – Chief Strategy and Information Officer
We were explicitly charged not to produce recommendations, so it was an explicit statement in our charging.

Judy Faulkner – Epic Systems – Founder
... next.

Paul Egerman – Software Entrepreneur
What happens next is up to ONC, which it happens with all of the workgroup efforts. But basically there are some alternatives for stage two. I hope that especially the patient download capabilities or something similar to that will be implemented. I'm pretty confident that ONC is going to do some of the test bed

approaches and it looks like to evaluate the architecture. Just having a new exchange architecture also hopefully creates a focus for future decision making.

Farzad Mostashari – ONC – National Coordinator
David Bates and then Larry Wolf?

David Bates – Brigham and Women's Hospital – Chief, Div. Internal Medicine
I just wondered if you could expand a little bit on what some of the operational feasibility concerns were felt to be. It seemed to me that there would be a number.

Paul Egerman – Software Entrepreneur
A fair number of those you can find in reading through the discussion about public comments. One way to understand some of the feasibility issues did relate to the, I'll try to summarize, the granularity, the suggestion of a more atomic approach to information exchange. So that created a whole series of operational feasibility questions about was that really going to be useful for clinicians, was it going to be a practical way for patients to express consent, was it really practical from the standpoint of doing population health, there was a lot of questions and then there were answers to those questions. But those were the kinds of questions that were asked. I don't know if you want to add to that.

William Stead – Vanderbilt – Chief Strategy and Information Officer
I think we could not identify in this industry or any other industry where these technical approaches had been put together at scale. That breaks out into lots of different operational potential problems. The impact on those of how thick or thin the index and search capability is, for example, and the clear tie between that range and the related policy requirements and the related governance requirements are examples.

Farzad Mostashari – ONC – National Coordinator
Larry and then David?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
First, thank you for summarizing that big and initially contentious looking report. One of the things I think is implicit in the report that I don't think actually gets enough discussion is the notion of push versus pull use of information. We tend to focus an awful lot on the push transactions, of I have some information about a patient and I want to pass it on to the next provider or I'm asking someone to take a step and there's a workflow part that's going on and we focus a lot on that. There's an assumption that's been the historic assumption that the current provider knows what information is needed in the next step of care, and it's all been very helpful and it's important to the comments about I need to communicate the plan, what do we intend, that's really coming from the current provider. But often in the course of care questions arise about what happened in the past, and we really have not addressed very much that whole area.

So I think separate from the details of the architecture here, the notion of a pull technology or a pull exchange that says I now need to know something that might have already been out there, how do I get that, and that we pursue how that's needed. Clearly, the most visible use of that historically has been emergency departments, and there are some HIEs that are focused on that as their use case, and generally their answer has been to build a repository, directly query the repository. And they avoid a whole lot of these issues because they've made some simplifying assumptions. But I think as we go forward we need to be looking more broadly at that, not just at the emergency case, but any transition of care. Someone who seemingly suddenly has a new problem, it wasn't on the problem list you got, but it turns out they've actually had a long history of this thing, and how you respond now would be different if you knew that history. There are many examples of that in almost every care transition, so I think this notion of a pull technology in our exchanges is a really important one to consider going forward.

Farzad Mostashari – ONC – National Coordinator
David?

David Lansky – Pacific Business Group on Health – President & CEO
I think the incremental suggestions you offer is to the two short term pathways during stage two that we might proceed, or ONC might proceed to move this agenda along with a patient centered pathway is very interesting, for lots of reasons, in terms of what we're trying to do. I wonder how much you've talked about the reciprocal consequences of that on the care delivery system itself. So in some ways there's an attractiveness to segmenting the experimentation of this model by having it go through the patient channel in effect and not disrupting clinical workflow and other functionalities that we contemplate for stage two. Kind of a back office set of adjustments to the data encoding and transmission and the patient has the capability of acquiring the data and potentially doing something with it. I do wonder, by the way, about the human readable requirement that we have and I assume it's not directly affected, but it raises the question for me about the human readability of the granular data that might be exported here.

But then do you imagine if this implementation test bed that's suggested here were to be deployed, with a patient-centric implementation app, is there likely then to be a set of consequences for the clinical workflow and the care delivery system of doing that? Or is this really a segmented method of beginning the implementation process, which insulates the clinical infrastructure from this new experiment?

Paul Egerman – Software Entrepreneur
It's an interesting question. If you look at the forward cases, what we've tried to do is to orient the cases in such a way that we would somehow minimize the need to address some of these policy issues up front. So what was really driving this first case, the push by patients between two points, is we felt that if a patient is directing it then that minimizes some of these privacy and security issues, so the patient is controlling their own data. Plus we felt it was a good starting point through the legislation since the patients have the right to their data and they also have the right to send it to a third party, so it seems like there was a legislative mandate.

We did not consider directly the possible clinical impact of doing a patient download, and I suppose that there is a clinical impact. We did consider that this was responsive to what was in the PCAST Report, however, the PCAST Report talked a lot about patient engagement and talked a lot about PHR systems, and so this was a vehicle that if people wanted to they could download their data and they could upload it in effect to the PHR system.

The other search is simple search and complex search have much more of an impact on clinical processes, and we put them in that sequence because when you get to simple search you introduce also the issue of this intermediary, this thing called a DEAS, so that has its own set of policy and technology issues associated with it. Complex search introduced some of the granularity issues, which has its own set of issues. So it was intended to be progressive and we had hoped that the first issue would minimize privacy issues and also minimize any change in workflow on the clinical side.

David Lansky – Pacific Business Group on Health – President & CEO
Can I just clarify that a little bit? I think I was getting more at the question of if the vendor does the engineering to meta tag the granular data elements to support the patient export function, does that implications for how that vendor would then in turn support clinical applications because the data has now been managed internally in a new way?

Paul Egerman – Software Entrepreneur
No, the way that that was suggested in our letter is that they would not need to do something special to each data element. The concept was something called a UEL wrapper, and Bill, correct me if I've got this wrong, but basically it takes an entire transaction, either a CCD or a CCR, which is an existing transaction and it in effect wraps it in such a way that it is consistent. It doesn't really cause it to have to change each data element, although the data elements within the CCD and the CCR actually already have metadata associated with it. But it's not a change to how the data is collected, so there's not a clinical impact there.

Farzad Mostashari – ONC – National Coordinator
Deven?

Deven McGraw – Center for Democracy & Technology – Director
I think you guys did a marvelous job on what must have been probably a tougher set of questions than we get routinely in this tiger team, because there were some of those questions embedded in your task as well. And in terms of what happens next in our adoption of this report, I suspect that among us there are widely varying views, just as there were on the PCAST Workgroup, about whether what was in PCAST is the right way to go, either as a whole or in terms of its parts. But I think you did a masterful job of trying to keep the value discussions out of the conversation and focus instead on the questions you were asked to address, which was if ONC decides to go in these directions, what would be some suggested ways to implement it? What would be some necessary questions that would need to get resolved? So I think given the body of work that's been put into this and the very clear focus on the set of questions you were asked, I don't see that we should stand in the way of moving this forward as it's written. We can talk all day about yes/no, do we like it, do we not like it.

Farzad Mostashari – ONC – National Coordinator
On the phone, comments or questions for the workgroup? Okay, Charles and then Judy?

Charles Kennedy – WellPoint – VP for Health IT
I guess one of the questions I never got straight in my head from reading the PCAST Report is what is the incremental advantage of what they're proposing versus HL-7 or MV3? How does it create incremental value? Why would we do something different than what it seems like the industry's been trying to do?

William Stead – Vanderbilt – Chief Strategy and Information Officer
Let me give a few dimensions that come into that space. The first is that our existing push transaction exchange infrastructure works when we know what we need to send and who we need to send it to. To the degree we're able to then aggregate and resend it through a regional exchange or whatever, that can be extended. That is quite different from being able to pull together all the information you need to make a clinical decision from whatever source. I at least forget many things that happened to me, and we all know the troubles of eyewitnesses and so forth. So there is real power to that idea and I think if you realize that this infrastructure could let you put that kind of idea side to side with pulling in knowledge, you might have a much broader approach to decision support. That's clearly one part.

Another part is that this idea of actually making the data liquid in the universal exchange language so that in essence the idea that people could write apps for data that could actually work within an existing system, much the way people write apps for iPod was I think part of their thinking. Another part of their thinking is this extensibility. The power of having a naming service for syntactic and semantic standards and for the versions of those standards so that whenever you receive a packet you can look up the standards that it is represented in and unpack, whether your system or you actually know anything about those standards at all. So it's all about approaches that scale to the macro scale in the way our business transaction processing world does not. I think that it could conceivably take a lot of the pressure off of meaningful use stage three if we move aggressively now in parallel, not in replacement, in parallel with what we're already doing. These things would sit side by side. They're not actually an either/or.

Paul Egerman – Software Entrepreneur
Let me just start with a comment. That was a great description. The way I would look at this also, well, from a user perspective, what the PCAST Report is suggesting is an Internet style approach to doing searches. So just right now I can do a search on you, Charles, and it's put in Charles Kennedy and PCAST, and I can find out any reports so that anything you ever said about PCAST .... And when you think about that, it searches all kinds of servers and gives you the information right there. Well, that's the same kind of vision that this PCAST Report has, is that instead of PCAST you could put in the patient's name and you can say you want to search about something, about your cholesterol count or your white blood count, and it would search. It would tell you all of the places that had that information available for you, about you, and you'd be able to view it. That is very different than the HL-7. It's closer to what Larry was talking about, a pull transaction, so again, ... on a complete solution for healthcare information exchange. You need these transition of care documents, you need the claim form transaction, you need all these other things. But this is a vision of being able to search all EHR databases as if they were one all over the country and find out information on a single patient.

Farzad Mostashari – ONC – National Coordinator
Neil?

Neil Calman – Institute for Family Health – President & Cofounder
I'm just beginning to understand this. I guess I'm not supposed to admit that, right? But it seems like it solves a problem that we talked about periodically, which is in the exchange of information if the sender's responsible somehow of figuring out what's meaningful to the receiver, there's a lot of guesswork involved in that. What's meaningful to the receiver can change in the course of a clinical encounter, so the first thing I might want to do is just glance at some information. But then as I find out more about what's going on with the patient I might want to search for additional information. At least in the models we've been talking about up until now, we've been puzzled, like if somebody's going to an orthopedic doctor you don't want to send the entire medical history and everything that's gone on for the last 30 years about that patient. But then on the other hand, there are some times when that might actually be needed by somebody.

So I think what this does—if it's really built from the recipient need point of view and a clinical encounter, is it allows people to first see something in a very basic and summarized way, but gives them the capability of drilling down. I'm asking this as a question, do I have this right, and then gives them the ability to drill down and continue to mine more information as they need it in the course of a clinical encounter. That's what this does. That's a huge additional value add to what we've been talking about, in terms of other discussions about exchange. Does this do that?

William Stead – Vanderbilt – Chief Strategy and Information Officer
Yes.

Paul Egerman – Software Entrepreneur
Yes.

Neil Calman – Institute for Family Health – President & Cofounder
Good.

M
And your comment, Neil, that you're beginning to understand what it does is also a very interesting comment here, because that's what the entire discussion with our workgroup is, after a while some people would start to get insights into how this all is going to work. So if you look at a summary document, in theory a summary document, it handles 90% of what you need to know. The theory is supposed to be what is the other 10%? The problem is it's like everything else, that last 10% is really sometimes hard. So you have to figure out how to get that right. There's a lot of questions about how to do that right.

Paul Egerman – Software Entrepreneur
Yes, but it also might make the information that's exchanged so much more useful because it might actually be that you only want to send 20% knowing that you could get any part of the 80% that you need. So it could make this process much more efficient. One of the things you hear from providers is do I really want to get all of this stuff and then be responsible for knowing what's in it and then having some responsibility conveyed to me about following up on things that really aren't within my purview but now I knew about and all this other stuff. And it kind of takes some of that discussion out and builds a clinical model where people actually can get the information they need, and it's got a lot of advantages. Judy?

Judy Faulkner – Epic Systems – Founder
A couple of things. First, I think that the test bed approach is a great idea. I think that the U.K. ... which they have spent supposedly billions of pounds on, and have not gotten the value that they expected from it is a good indication of the importance of doing testing first to make sure whether something that is untested will really work. When there was the PCAST meeting that we had in D.C. a few months ago, it was said that it was going to cost healthcare organizations about $2 to $3 a patient a year, which is not

inexpensive, and it would be a 5% to 10% increase in cost. But I don't know increased compared to what. I do think that it does appear that we have to figure out where is there overlap between what is already being done and what the HIEs are doing.

There's another issue I wanted to bring up, and that is that I think the PCAST Report aspirations we're all in agreement with are very good. But what is showing up in the blogs, I have seen them sometimes myself and I have been told about this, because I don't read very many blogs, is that we have to be careful of an apparent conflict of interest. That is, if in fact the primary spokesperson for PCAST does have products that would benefit tremendously by this, do we get into, and I know we're not supposed to judge, the uncomfortable position of appearance of conflict of interest? So I wanted to bring that up because it's in the blog.

Paul Egerman – Software Entrepreneur
It's a great issue. It's an interesting issue because it was an issue that as we dealt with the entire process and handled as a side issue people would send me an e-mail and say what do you think about this, and for whatever reason people weren't real comfortable talking about that issue. But to me the way I respond to that issue is, like I said, there's a reason in the letter we call it the New Exchange Architecture as opposed to the PCAST Architecture. The way I look at it is PCAST did its job. PCAST put forward a great report. It has this compelling vision. They put this on the front burner and they did a priority and we ought to say thank you to PCAST for doing that. But now instead of being the PCAST Architecture it should be the ONC and HHS architecture and we need to own this architecture from a number of standpoints. It's not going to succeed if the people working on it feel like it's imposed on them. They need to feel good about it, they need to own it, and we need to do it what is the right thing for the country with it. So that's why we call it the New Exchange Architecture. That's the starting point.

We should go through these test beds and it will incrementally change. And I can't predict how it's going to change, but my suggestion was to take the PCAST name off of it to change who are the people who are advocating for it, and Farzad and ONC should have to own this and change it however is appropriate to make it successful. I don't know if you feel that's responsive to what you're suggesting, Judy?

Judy Faulkner – Epic Systems – Founder
Yes. That's I think a very good way to approach it. The question is if in fact the PCAST Report does really push the need for everyone to use a PHR with the ability to have apps on it, there are a limited number of those, and middleware with the ability to have apps on it. There are a limited number of those that are out there, then I think it is a challenge, though, to ONC to figure out that apparent conflict of interest and what choices are there, what directions are there. But I do think still that most of us have agreed that the aspirations are good aspirations.

Paul Egerman – Software Entrepreneur
Again, if you look at the progression before use cases, the first one relates to patient engagement, which I think is outside of this other discussion. In fact, it's a good thing to do and a simple search probably does not require the middleware piece and does not deal with the granularity. So there is an opportunity here to work through these issues and in the letter we even asked, in two places in the letter we even suggested maybe there was an architecture or there's no external index at all, or at least no external data element index. And, those are important issues to address, because if you come to an architecture where there's no external data element index, then a lot of these policy issues become simpler. Or to put it differently, the less data that's externalized outside of the family of the providers that treated patients, the less data that's externalized, so less concerns there are from a privacy and security standpoint. So those are all valid questions, so that's at least my response. You raised a very good question, and I don't know what else I can say beyond what I've said, though, to it.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
If there are no further comments or questions then I'll facilitate the motion process that's going to the man on my right here, to entertain a motion to accept a letter without recommendations about their analysis of the PCAST letter and presenting some options to ONC.

Judy Faulkner – Epic Systems – Founder
Thank you.

W
I'll make a motion.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Second? All in favor? Opposed? Abstentions? All right, well thank you very much to the two co-chairs. Thank you, Paul and Bill and the PCAST Workgroup.

Judy had asked the question, what happens next? I want to give some sense from ONC's perspective in terms of what happens next. I think the options provided in the letter from the workgroup are very creative and very smart about identifying the way to move forward that leaves options available. Yet makes concrete substantial progress forward in terms of a whole variety of future uses and use cases, whether it's—and particularly starting with the UEL and metadata and finding a hook for beginning, starting somewhere. Let's just start and starting with sharing the information with the patient, which, as Paul pointed out, really involves many fewer of the really particularly thorny policy issues we have to work through when we're talking about the external entities and the amount of information they would keep and the governance around those and so forth.

So, I think it's a very creative and smart option as a way to move forward that could permit searching and segmentation within the record that could enable consumer mediated information exchange, trying different feasibility, operational feasibility and, frankly, the psychological feasibility of patients exerting granular choice over specific data elements within that. We think it's a very important piece and we've already begun the work to look at whether there are existing standards for the metadata elements that would be included in the UEL around identity, providence and preference.

Now, this is new, and those existing metadata standards may not be appropriate. We may need to do more work on that from the standard's side and we're going to be presenting this to the Standards Committee and they're going to be the ones ultimately to make recommendations to us on the incorporation of standards into stage two of meaningful use. And I think what would be wise for us to do would be as soon as possible, not waiting until the NPRM in December, but as soon as possible getting structured feedback on those particular metadata standards that we will have initially identified as being suitable potentially in the UEL as it was proposed. So, I think in the early summer timeframe we hope to have assembled enough through the standards interoperability framework to be able to put out advance notice or proposed rulemaking or an NPRM that would—depending on the level of maturity of those standards, in order to get a lot of comment and feedback on how the suitability of those metadata elements that might be included then in a December NPRM having to do with the certification criterion standards.

Meanwhile we are going to continue hard at work on doing those pilots and test beds. We have some breakthrough grants to our state HIE grantees in Indiana and Montana specifically looking at this issue. There may be opportunities within the federal government to look for platforms for doing this sort of experimentation and learning. I think we also have to continue working on the other building blocks as the report letter identifies this is one piece. The technology is one piece, but we also need these other building blocks whether it's around patient matching, whether it's around identity assurance, whether it's around governance and policies for patient choice, meaningful choice when it comes it query, a query use case, in general. So there's a lot of work to be done and we're going to make it our own, Paul. We're going to move forward on something that can really meet the vision, but also be feasible to implement and start the conversation toward the goal that Neil articulated.

M
Sounds great.

Farzad Mostashari – ONC – National Coordinator
Thank you.

Paul Egerman – Software Entrepreneur
It does sound very good and the concept of the patient push in the portal has a lot of capabilities to it. It does impact the meaningful use stage two because one of the things we got in our hearing was a comment, I think that Carol Diamond made, is when patients start to get access to the data you have to like cleanup for company. So you have to suddenly realize the data has to look right, so some of these things that you see in meaningful use stage two you want to make sure your problem list is up to date and your medication list is up to date. Well, one vehicle for doing this is patients start looking at it and you start causing that, that's pressure to make that happen and that's a positive thing. So, it's an exciting journey.

Farzad Mostashari – ONC – National Coordinator
Thank you. Moving on to a presentation on the Federal Health IT Strategic Plan Overview with Jodi Daniel and Seth Pazinski.

Jodi Daniel – ONC – Director Office of Policy & Research
Thank you, Farzad. I think this is actually a great way to close out this morning's discussion after we've had conversations about national quality strategy, moving forward on our strategies and discussions about meaningful use. How the PCAST kind of looking at the vision and the future and how we might have a really more robust learning healthcare system. I feel like it's actually a great conversation to wrap up the morning discussion as well as a great time to have this discussion with the changing of the guard and with Farzad taking the leadership and kind of picking up our strategy and our vision from here out.

We did actually publish our strategic plan on March 25th, due in large to the help of Seth Pazinski, who is sitting next to me who helped manage the workgroup of the Health IT Policy Committee, which gave us some great input and was a really important foundation for what we did. I think Paul and his leadership on that Committee and on that deliverable to us. We've really gotten both a lot of great input from you all. There are some things that came up in the process that influenced our strategic plan. So what I'd like to do today is walk through a little bit about our process, what the plan says, how it relates to the broader HHS plan and also how it relates to the strategic framework that you all presented to us about a year ago.

This plan is really important to you all in guiding our federal efforts and investments in health IT over the next several years. We were mandated by the HITECH Act to revise our strategic plan, but quite frankly it's something that we really had to do, whether or not it was something we were required to do in the Act. Because so many changes that have come up through the HITECH Act, through the Affordable Care Act really influenced our strategy and our direction and really required that we took a second look at the strategic plan we had published in June of 2008 to consider how we move forward and what our vision is in light of those changes. So, the scope of our plan, this is the Office of National Coordinator Strategy for realizing Congress' and the administration's health IT agenda. What we did was really take a measured look at what we were doing, what the federal government's role is in trying to meet the objectives that Congress set forward and the administration set forward for all of our work.

Let met talk about how this fits into the broader HHS strategic plan. The HHS strategic plan has five goals in it. The first goal is transform healthcare. There's a specific objective within the HHS strategic plan within the goal of transforming healthcare related to health IT. So it's really important in thinking about where we fit in and where the work and the discussions that we've all had fit into this that this is really not about the infrastructure, but it's really about tools to transform healthcare. Our plan really looks at these tools and looks at how we can use health IT to improve care coordination, patient engagement, etc. So, it's part of the HHS plan and it really fits in what I think is the key goal in the plan and sort of establishes how health IT is about transforming healthcare in the broader sense. So, in looking at how can health IT transform healthcare, and we walked through this in our plan, it's taking health IT backward, health information technology, starting with focusing on better technology is how we can get to better information and therefore better health and transformed healthcare.

We talk about our 2015 end state, looking at enhancing the ability to study care, delivery and payment systems, empowering individuals and increasing transparency and improving care and efficiency of

population health outcomes. So, we are looking at this in the context of how it fits into that broader HHS goal. It's something that this Policy Committee identified as an important perspective that we needed to look at in our plan, something the HHS strategic plan also envisioned and it's something that ONC really thinks and focuses on in looking at our programs, our policies and our efforts.

So, I want to just take a step back a little bit and look at our process just to show you where we've come and the kind of input we've gotten. So, the stars are indicating where we've gotten public comment, including the public comment period we're in right now just to highlight how important we see stakeholder input into our process, both the input of this group as well as the broader public input. We also have input from our federal partners. We worked closely with the various federal agencies to make sure that we were understanding what they were doing, what their objectives were and how we can align the efforts of the different federal agencies in our plan, which I think was really both valuable and helped to shape our thinking on our strategic plan and what our priorities were.

I'm not going to go through, because this is supposed to be a fairly short high level presentation, I'm not going to go through all of the details of the plan. It is in the PowerPoint. There is some information. We have five goals and there are objectives and strategies for each goal and the plan goes into a lot of detail about how we meet each of these goals through those objectives and strategies. I just want to kind of give the framework of how we see the plan in the context of moving from better technology to better information to transformed healthcare.

Just very briefly; Goal one, achieve adoption and information exchange for meaningful use of health IT. This is sort of a centerpiece of our strategy and one of the key critical components in our plan. Goal two, improving care, improving population health and reducing healthcare costs through the use of health IT. This really aligns with the Affordable Care Act goals in connecting health IT to the objectives in the Affordable Care Act. Goal three, inspiring confidence and trust in health IT. This is focusing on how we match our privacy and security policies in light of health information technology and understanding that this is a key component testing successful in health IT and health information exchange.

Goal four, empowering individuals with health IT to improve their health and healthcare: This was actually based on input and discussion from the Health IT Policy Committee that we needed to elevate the importance of consumer engagement and consumer empowerment in our strategy and in our plan. So that's what this goal is all about, rather than peppering it throughout the pieces of it to really elevate it to show the importance and the centrality of empowering consumers when we're talking about transforming healthcare through health IT. And the fifth kind of goes to the longer-term vision of achieving rapid learning and technological advancement through health IT and health information exchange.

So, I'd like to explain how we see this connecting with what you all recommended to us. So, I'm going to bring you back a year and do a little step backward in time. But I really wanted to, one, compliment all of the hard work of the Policy Committee in thinking through a strategic framework because it significantly shaped our thinking in our strategic plan in both helpful and important ways. Most of what was represented is represented in the strategic plan, with a little bit of a difference in shaping a couple of things added based on some changes that came about from some discussion and from some little things like the Affordable Care Act being passed after most of the strategic framework was drafted.

I'm not going to go through all of the arrows, which some of the ONC staff called the Washington, D.C. Metro map because of all the colors. You could follow this and maybe get lost in transit, but let me highlight some of the things and how the strategic framework that you all developed and forwarded to us mapped to the strategic plan in a broader way. So, if you look at the pyramid that was in the strategic framework there's the policy and infrastructure, which is sort of the backbone and the basis for the above three goals, so the Learning Healthcare System, meaningful use and privacy and security. And you'll see the Learning Healthcare System, meaningful use and privacy and security map directly to goals that we have in our strategic plan, so goal one is about meaningful use; goal three is about privacy and security and goal five is the rapid Learning Healthcare System, so those are directly mapped to our strategic plan.

There are two new goals that we have put in. One was goal four, which is about empowering individuals. Like I said, I remember when Paul and I were sitting up here talking about the strategic framework and folks were giving us feedback and over and over again people were talking about, well, you need to get the consumer in that strategy, you need to really highlight the role of the consumer here and here and here and here. There was some conversation and some comments about elevating that because it kept coming up over and over and over and over again. And we took that seriously and we have elevated that, I think to the credit of the discussion here and some forward thinking. The other was goal two, improving care, improving population health and reducing healthcare costs through use of health IT and this was really developed, aligned with the Affordable Care Act and the passage of the Affordable Care Act, which was right at the tail end of our strategic framework development process. So, really trying to articulate how we align our health IT strategy with the objectives and goals of the Affordable Care Act and health reform.

There are a couple of places where we are aligned with the national quality strategy, which we had a presentation about this morning. Specifically, we have in our strategic plans some spotlights on health and health outcomes, if you look at our strategic plan. We're trying to align what we're putting forth as goals, objectives and strategies to specific health outcomes, including cardiac care, so you can see that peppered throughout in how we're thinking about these strategies and objectives, really mapping to healthcare outcomes. So, I think that that's very timely and will help shape our programs and policies as we are implementing our strategic plan.

I know this is a very quick, high overview. We're happy to take questions. I also wanted to say where we are in process. We are open for a public comment period right now. I've given the link for folks who want to comment on our strategic plan, please do. And we will then come up with a final plan. Seth, what's the time?

Seth Pazinski – ONC – Special Assistant
Early June.

Jodi Daniel – ONC – Director Office of Policy & Research
Early June. So we really look forward to that feedback. Again, we really appreciate all of the feedback that we got from you all in thinking this through. I think it really gives us a great framework to think about how all of our different programs and policies align with each other and with some of these other broader initiatives that we heard about today and that we've been hearing about over the last few months. So, thank you. Happy to take questions.

Farzad Mostashari – ONC – National Coordinator
Deven.

Deven McGraw – Center for Democracy & Technology – Director
I know, I forgot the tent card; tent card, raise hand, I'm a little off. I'm thinking you guys did a tremendous job with pulling this together and I'll have an embarrassment moment of my own, that I haven't actually read the whole thing, again, in detail. I got through goal one, though. But it does occur to me as sort of looking at goals one and two, in light of the conversation we had this morning, I think we have to be very careful to continue not to silo meaningful use and achieving it as though it's separate from other programs that are aimed at really achieving goal two, which is improvement in care outcomes. One might also argue that consumer engagement is part of this overall package of driving to improvements in the healthcare system. It's almost as though meaningful use is not necessarily the end of itself in the way that we used to say health IT is not the end of itself; it's really about tying meaningful use into the objectives that we want to achieve in the system.

So, I'm not suggesting that the two categories be collapsed because consistent with the approach we've taken all along, the escalator metaphor about you have to start with at least getting the adoption and the data into the system before you can start running up to the goals we want to achieve. It's more of a cautionary note in light of the discussion that we had this morning, in light of how we're being encouraged to think of meaningful use as part of a bigger strategy and not just, again, a siloed component.

Jodi Daniel – ONC – Director Office of Policy & Research
That's really helpful feedback. I think you actually articulated for both of sides of that, like why it's good to pull it out and why we should think about how it fits together. I think that's true on a couple of the goals. I think you could say the same thing about privacy and security. It's not an end of itself. It's something that is a necessary infrastructure, a necessary policy and technical capabilities that we need in order to seed the longer term vision.

So, that was challenging. We added that in because we wanted to make sure—because we had these other four and we really wanted to make sure that we had our eyes on the prize. That we didn't just have the pieces along the way that can get us there, but we showed that we really had as one of our goals to get to the outcomes and that these were kind of pieces of it. Maybe we can think about how we organize it and if there's a way to kind of structure that.

Deven McGraw – Center for Democracy & Technology – Director
I don't think it needs to be changed, but it's just in light of a lot of really interesting discussion that we had this morning it occurs to me that we have to be careful not to look at it as a stand-alone objective.

Jodi Daniel – ONC – Director Office of Policy & Research
That's a great point.

Seth Pazinski – ONC – Special Assistant
And I think one of the nice things about the scope of the document is that it's not an ONC plan, but a federal plan. So it's broad enough that it can bring in everything that federal government is doing, so I think Tony earlier and Neil, I think, made comments about the role of ACOs and the Ameriforums and that's represented in the plan.

M
Thank you. I did spend some time reading through the strategic plan and enjoyed the change from the prior framework. I think it's well done and I hadn't thought about it as a subway map, but it looks like we're on our route. One of the things, what's changed graphically is that the Learning Healthcare System was at the top. As I looked at the performance measures table the Learning Healthcare System is sort of left to the bottom and has no performance measures defined yet. So the discussion we had this morning about ACOs, 5010, ICD-10; all of these are issues that we're learning about and Larry mentioned as well those early adopters and what we are learning from them about meaningful use and how that might inform us about stage two and stage three. So, I just wonder if there is a plan to fill in some of the performance measures around a Learning Healthcare System.

Farzad Mostashari – ONC – National Coordinator
I think maybe, and Chuck is the room; Chuck has been leading our activities in thinking about the technology and policies necessary to create a continually learning healthcare system, which I think goes far beyond the kind of quality improvement aspects of how do we do better, how do we learn from what we've done and do PDSA cycles.

It's really thinking about what is, in a sense similar to the PCAST vision. How can we have an architecture that serves patient care, but also serves the ability in a distributed way, asks questions of data, for the questions to go out to the information and for answers to come back and to be able to do that and all of the pieces, technology and policy and standards necessary to accomplish that. We do want to move forward on that aggressively. It is not clear to us at this time what the metrics for that might be, but I think it is something that we would love to get comments on, something that is feasible for us to hold ourselves accountable to and drive towards.

Farzad Mostashari – ONC – National Coordinator
Good. We can have a little bit longer for lunch. We've held you extra this morning. It's been a cruel morning, so apologies for that. Paul will be continuing the chairing for the afternoon session. Thank you.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
For once we have a whole hour so that we can eat lunch rather than wear it, and so we'll reconvene at 1:30.

(Lunch Break)

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, operator. I'll turn it over to Dr. Tang.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Okay, welcome back, everyone, and I think everybody has had a chance to eat and for those who are on the phone, cake has been distributed to everybody in the room, I think. We don't know the source of the cake, so you might want to watch somebody else who's eating it first. But, thank you to whoever ordered it.

We have four presentations this afternoon and I think some are going to be shorter than the allotted time, so we'll probably finish not as late as we had anticipated. We're going to begin with the Privacy and Security Tiger Team. They do have a set of recommendations they'd like us to review and approve, so take it away Deven and Paul.

Deven McGraw – Center for Democracy & Technology – Director
Thank you very much. Paul and I would like to take credit for the cake as a sort of promotion of our recommendations today, but unfortunately there's probably someone in this room somewhere who is actually responsible for said cake. So, I'm afraid in all honesty we can't. We do have some recommendations to put before you today. Some of them you have seen before. We've at least had an opportunity to open up the dialogue on, but we're trying to finalize those today.

I want to start, though, by thanking all of the members of the tiger team, as usual, who are listed here and the members of the public who follow us and give us their feedback. But I also want to take a moment to thank my co-chair, who has been under pretty pressing duty over the last couple of months, also chairing the PCAST Workgroup, which I think as you can see from the final product was a very intense experience and yet he was always there as my co-chair for this piece, too. So, thank you, Paul. I really appreciate it. It's nice to have you back full-time, but you were always there for all of this.

Paul Egerman – Software Entrepreneur
Well, I appreciate that comment, but I'll just say right back at you. It's great to see your leadership on these efforts that are so critically important.

Deven McGraw – Center for Democracy & Technology – Director
Thank you, Paul. So, here are the general areas of our recommendations today. EHR user and user within a provider, as distinct from a patient because we have a separate set of recommendations on patient; authentication, some privacy and security recommendations for patient portals; some recommendations regarding stage two of meaningful use in the security risk assessment objectives. Then finally, we just have a little bit of clean up to do on some patient matching recommendations that the Policy Committee has already approved, but we need to send the official referral on to the Standards body to do the work that we had already prioritized for them.

I also want to bring to your attention, if you didn't notice it from Judy's e-mail that we have both a set of slides as well as a recommendations document. The document is helpful because it provides a lot of the context for the conversations that led to the recommendations. That's the kind of depth of thinking that you can't fit on a slide and that also helps ultimately when you turn it into the transmittal letter to have that be something that stands on its own and that people reading it without having the benefit of the conversation can actually understand. So, I hope you've had a chance to read it, but we will likely, in presenting the recommendations Paul and I may refer to that. Because it's quite possible that some questions that you have might actually be addressed by some of the text in the letter and we just couldn't squeeze it on the slide in an effort to be parsimonious with our slides.

With that I'm going to turn it over to Paul because he's going to lead us through the first category of recommendations.

Paul Egerman – Software Entrepreneur
This workgroup does have recommendations. There are four categories. The first category relates to this concept of EHR users and authentication and to remind everybody what an EHR user is it's anybody who uses the EHR system who is not a patient. In other words this is, for not only clinicians, but it could be administrators or executives or administrative personnel. So, these are the people that would be using the EHR system.

To look at the first bullet, item number one, basically to refresh everybody's memory we had a discussion one or two Policy Committee meetings ago where we discussed two factor authentication for EHR users and asked for some guidance from the Policy Committee and a couple of comments were made that were very important. One was this sort of realize that as we move to this new world of information exchange and we have this entity NWHIN, that in some sense security is like the security of the air traffic controller system, which is the weakest link anywhere in terms of where you get in is potentially a problem.

What we decided to do is just to match the concept of two factor authentication to participation in NWHIN as opposed to matching it specifically with certification. So we'd say if you're participating in NWHIN and Information Exchange then you have to have two factor authentication as a baseline. In other words, that's not necessarily sufficient in all circumstances, but it's sort of like the minimum necessary. We also said you needed it for this concept of what we call remote access to the EHR and we defined remote access as access over a public network like the Internet and we also suggested ONC might want to seek some public comment on this issue. So, that's the first point; so, it's two factor authentication for participants of NWHIN.

Second concept, very important, organizations and entities can adopt more stringent requirements. In particular there's some sense of high risk transactions where additional authentication of greater strength maybe required and we list out some of these when we say Policy Committee and ONC may wish to do some additional work to help identify some of these use cases where additional authentication is used. The fourth point was that policy should be reassessed for consistency with other national identity efforts and technology developments. The observation here is it's a fascinating area, the whole issue of identity assurance and authentication and there are national efforts underway, especially as it relates to the Internet and there are a lot of technology developments and so presumably these policies may need to evolve over time.

We also said ONC would play a role in developing and disseminating evidence about the effectiveness of various methods for authentication and then item number six here says, "For stage two of meaningful use this really is not a meaningful use recommendation. It really should be rephrased as a recommendation for certification criteria for stage two meaningful use." There are two bullets. So, again, if you thought of the first things I said before relating to NWHIN or NwHIN governance, this part does related to stage two of meaningful use.

So, for certification criteria the first bullet is eligible providers and hospitals need to obtain digital certifications. This is related to a previous recommendation the Policy Committee approved. These are digital certifications at entity level for certain type of push transactions. So, there's a certification recommendation there and there's also one relative to e-prescribing with e-prescribing of controlled substances. The EA now has a rule regarding what you have to do for authentication, which is a bit stronger than just saying two factor authentication and so we're saying the e-prescribing modules should be certified against the DEA rule for e-prescribing of controlled substances.

So, that's the EHR user authentication and now, Deven will take us through the patient portal.

Deven McGraw – Center for Democracy & Technology – Director

Thanks, Paul. So, in anticipation that there very well could be either as a meaningful use objective in stage two and the use of a portal within an EHR for patients to be able to view and download their information, even if that were not a criteria in stage two and maybe was one in stage three. For example, you would still need for there to be the technical functionality of the portal in order to meet that and that certainly is something that if we were going to head in the direction, we need to get the ball rolling on the technology side sooner rather than later.

What we have to say about patient portals today was very much focused on the technology issues that are tied to policy and very much focused on privacy and security aspects of portals. Versus thinking about some other policy issues that one might want to consider in terms of usability, for example, for patients with respect to a portal; transparency issues about just exactly what is being introduced here for patients so that they fully understand both their risks and responsibilities. So, you might call this a sort of portal snapshot, but, again, we sort of felt the need from a timing perspective to at least get some recommendations that would be needed to be supported by technology up for your consideration so that there wasn't undue delay in getting that ball moving. So, in that regard we have some recommendations on identity. We have some recommendations on authentication. There's a slightly common theme here. Then we have a few other recommendations on portals that are related to privacy and security issues.

With respect to identity proofing we talked a lot about whether we would set a requirement, for example, that says you have to have two forms of ID or you have to present a picture ID or you have to present this or you have to present that. Inevitably—and it didn't actually take us that long to reach this conclusion—we really felt as though entities would need to make their own determinations of what would be required to identity proof their patients based on their own assessments of how to address the risk of inappropriate access. But while also setting those requirements in a way that encourages patients to actually open the portals and to use them.

So what we did was come up with a set of guiding principles that could assist providers in identity proofing. These are expressed in a lot of detail in the letter and we decided not to put them on the slides, but they include things like, again, it's a balance, obviously, the entity. The provider entity is the one at risk of inappropriate access, but at the same time if you were to set the bar so high for either identity or, quite frankly, authentication, you might end up with nobody signing up because the requirements are so onerous. In person identity proofing might feel the safest in terms of I can visualize you and it probably could be an easy part of work flow. At the same time if everybody has to come into the office in order to open up their portal, it's not going to be that easy for people who live in remote areas and might want to have that access to do that.

We also had a recommendation, Christine, you'll probably like this one, of talk to your patients and get feedback from them about what is likely to work, which is definitely something that the VA has done. We had a nice presentation from them during one of our calls, that their My Healthy Vet portal includes a view and download function today that's used. So, the next set of recommendations is that, you know, the healthcare industry is not approaching these identity issues in a vacuum. There is actually a fair amount going on within the federal government on identification and, in fact, I believe today or tomorrow the national strategy for trusted identity in cyberspace is going to be released by the Department of Commerce.

We need to make sure that healthcare is part of conversations that are taking place within government about what are the best ways to identify and authenticate individuals for access to information over the Internet. Not to necessarily look at these innovations just in terms of how they apply to healthcare, but also what we might be able to learn from other industries. So, as Paul put it, this is a rapidly evolving space and ideally we would set up processes that involved guidance and regular assessments about what's working and what's not working in order to keep the work that providers are doing in this space up-to-date with what else is going on in the industry.

In terms of authentication, as a baseline providers should require at least a user name and password to authenticate patients and now, that's as a baseline. Just as in the provider/user space if physicians want to require more to authenticate in order to provide a more secure portal. We're not barring them from

doing so, but consistent with the principles we set forth, obviously, there is a bar that you can set so high on authentication that you make it difficult for people to accomplish this or they create workarounds. So, one of the examples that gets put up a lot is if there's a strength of password requirement that requires it to be longer, it's complicated and people write them down on little stickies on desks in order to remember them, that doesn't really accomplish very good security. So, there's always that balance. But given that the likely mode of authentication for a lot of these portals is going to be just a user name and password to get in, we thought it would be helpful for the certified EHRs to have a capability to detect and block programmatic attacks, or attacks from someone who might be known or unauthorized, such as a disgruntled family member.

There is technology that can help detect these and then it has an auto lockout function so that somebody can't get in. We're just asking for this requirement, that the technological capability be in the systems, whether or not it's actually deployed by an individual provider or not would be, obviously, in their discretion, but at least the tool would be there for them to do that. And then once again, and there's a typo on this slide, as the identity space is evolving, so is the authentication space, so ONC should work with NIST to provide guidance to providers on trusted identification methods. We said that already; we meant to say trusted authentication methods on this particular slide. It's right in the document; we just missed it on the slide.

Then in terms of other privacy and security recommendations for patient portals we think audit trail functionality is important. Providers and hospitals with portals should deploy audit trails for the portal and at least be able to provide them to patients upon request. Similarly, there needs to be some provisions for data providence, which is accessible to the user in some way, both in respect to information at the point of access as well as it's downloaded. Obviously, there are some details to fill in about what exactly would be the components of this data providence and how it would be expressed, how it would be accessible. So there are more details to work out here and this is probably one where there is some work to be done.

Oh, here's the PCAST report coming back to bite you. I would now have known what this was until PCAST educated me. It's data about the data; where did it come from, who created it, on what date was it created.

Paul Egerman – Software Entrepreneur
Yes, it's almost like ancestry.

Deven McGraw – Center for Democracy & Technology – Director
Yes, the family history of the data.

Paul Egerman – Software Entrepreneur
But it's like dates, provider kinds of stuff, but it could be very specific. It could be the lot number of the medication. I don't think you'd go that far in a patient portal.

Deven McGraw – Center for Democracy & Technology – Director
Right, device number is providence arguably. Then our last recommendation in the portal space is that the portal should have a mechanism to ensure that the information that's in the portal can then be securely downloaded to a third party who is authorized by a patient, like a PHR, for example. This, again, I think there's some further discussion about what that would look like from a technical standpoint. But we wanted to lay the groundwork for further technical work to be done by teeing up for you all to consider recommendations that these are some sort of basic, minimum privacy and security related functionalities that ought to be in a portal.

So, moving onto category three—and we're close to the end actually.

Paul Egerman – Software Entrepreneur
Security risk assessment, there are two parts. It's an interesting recommendation. Basically, stage one of meaningful use required a risk assessment to be performed so the first part of our recommendation is

to suggest that that should happen, again, in stage two. This is a healthy and good and reasonable thing to do. Then the next part of our recommendation is an interesting recommendation. It relates to something that occurs right now that has been nicknamed the wall of shame, that basically when a laptop is lost, when a backup tape is lost you get an opportunity, the eligible provider or hospital gets an opportunity to be listed on the wall of same. In other words, the fact that this has occurred is disclosed and you have to notify the patients.

There is a whole process that occurs and the concern that's been expressed about this is that when these events occur, first, unfortunately there are a lot of them occurring, but when they occur it's sort of like big time local news. In other words, it's on radio. It's on television. If anybody still reads a newspaper, a local newspaper, if those still are in existence in the local area it will be front page of the local newspaper that these things occurred and the problem with that is that damages public confidence in these systems and, in fact, it's not good for anybody. It costs money for the eligible providers; it's got to be frustrating for any vendors that are involved. There's really a lot of bad things that happen as a result and the feeling is that a lot of these things are happening because people aren't paying attention to some of the things they're supposed to already be doing.

What we suggested as part of the risk assessment is that providers and eligible hospitals should have to attest that they are addressing the encryption and security functionalities for data at rest. The concern that we had is that because this is something that's called addressable, a lot of people don't understand what that means. Just because it's called addressable in the regulations doesn't mean you don't have to do it. It means that you have to either do it or explain why you're not doing it and what security provisions you're taking as an alternative, so that relates to, a lot of people are concerned about this as it relates to data at rest in the data center. So, they'll say, oh, it's expensive, it's time consuming; we don't want to encrypt that data. Then the answer is, well, that's okay as long as you have securities policies in place, around the media, around disposal of media, that you're aware that this is what's going on.

It's questionable whether or not you should take that same approach with what's called cold backups, which are like tapes and other things, maybe those should be encrypted, at least security processes have to be in place and processes really need to be in place for laptops and all these various mobile devices. So, the recommendation is that as part of the security risk assessment that the eligible providers and hospitals have to attest that they have read through this and understand what they're supposed to be doing and they've addressed this issue. Now, in some sense, that's not creating anything new. This already exists. We're not asking for anything new and in that context it might be viewed as controversial, but what we're trying to do is simply shine a spotlight in an area where we perceive there to be a problem. With the hope that by shining a spotlight on this area that problem might be mitigated, which would be in everybody's best interest.

So, that's the security risk assessment. I would tell you the fact that this issue is not well understood was clear when we had our discussions within the tiger team meeting, because there was a lot of confusion about what we were trying to say. We had to make sure we worded it exactly right to make sure people understood that we're just trying to get people to understand the way it currently exists and to make sure that they're doing what they're supposed to do, which is addressing the security issue.

Deven McGraw – Center for Democracy & Technology – Director
Thank you, Paul. There is a lot of text in the letter that goes through much more carefully sort of why we came to the decision to shine the spotlight on this particular addressable implementation specification under the HIPAA Security Rule. Again, it bears repeating because our recommendations get mischaracterized quite often. We are not putting before you a requirement to encrypt all data at rest.

What we are saying is do what's required of you under the HIPAA Security Rule with respect to the addressable implementation specifications of encryption of data at rest. We're going to use the meaningful use criteria and ask you to attest that you have, in fact, addressed this as a way to shine a spotlight on it. And see if we can't make a dent in the number of institutions that have had to report breaches of data under the new breach notification rule, most of which have involved losses either due to theft or out and outright loss and none of them protected by encryption.

So the last set of things that we have before you today have to do with the patient matching recommendations that you as a Policy Committee have already approved. So in many respects this is merely a formality of making sure that they Standards Committee gets the set of instructions that are related to implementing the recommendations that you all have already approved. That includes identifying standard formats for data fields that are commonly used to match patients specifying the standards that apply when demographic data is missing and how that gets expressed. Considering whether a USPS address validation and normalization would be beneficial to improving matching accuracy and then testing of the EHRs to make sure that appropriate transactions can be sent and received with the correct formats and that the data entry sequences actually exist to reject the incorrectly entered values.

With that, I'm sure there's lots of questions, but it was helpful to be able to get that all through and out so that we can maximize our time. We are open to questions.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I'll start out then. Thanks for the great work on this subject. I have a couple of questions. I think one at least is just a clarification, one is a question. I'll start with that one. When you talked about the identity proofing for patient portals and you basically said the local organization should do whatever they think is best. In security isn't it the Achilles heel that wherever the least robust identification and proofing in this case, won't that determine the case for the whole set? So, when HIE becomes; it's a skate to the puck thing, so when HIE becomes widely available then you'll certainly have patient data flowing and wouldn't a potential threat be wherever the organization access the information at the point where they have the least amount of identity proofing?

Paul Egerman – Software Entrepreneur
Good question. When we talk about patient portal, it's important to sort of define what is meant by that. A patient portal, at least in this context is the ability of a patient to view their own record. You know, they probably have, at least at this stage, minimum opportunity to change anything. They may have some secure messaging capability in some patient portals where people pay bills or look up appointments, but there is a very limited functionality that says the patient may view, and probably can't even view their entire, certain aspects of their own record.

That's not the same as HIE. In other words, being able to sign on, if I'm a patient at Palo Alto Medical Foundation, I can look at my patient portal at Palo Alto Medical Foundation, but I can't go from there anyplace else. In other words, I can't access information from there into Kaiser or some other entity, so it's not quite the same as health information exchange. We did try to determine, gee, is there some; what would be the impact of going to a two factor for patients also? The feeling we had was well, we want to encourage patient engagement and so in this constantly, whenever you do security you have this issue of balancing utility and risk. So the issue was we wanted to make it easy for patients to access their records. We didn't feel that the risk was really strong enough that you had to do more than a single factor.

Deven McGraw – Center for Democracy & Technology – Director
Well, you could if you wanted to, but in terms of the baseline requirement. Again, this is a firewalled off view already from the rest of the EHR with functionality that's patient specific, but not greater than that. I guess I would toss it back to you, if you wanted to set national policy on identity what would it look like and to what extent would a national policy that, for example, required a government issued ID have on some patient populations. That depending on your provider and the populations that you serve, what would that mean whether everyone who wanted one could get one? It's very hard to set one single national standard here and we already have entities on the hook for a breach, quite frankly, and so it really is up to them to decide how they're going to deploy this in a way that keeps that safe. I don't think it's the weakest link argument because, I'm in agreement with Paul. The access is limited to what the entity has made available for the patient to see and that's all.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

So, let me clarify the question. There are two different topics we can discuss. One was authentication; I think that's what you were referring to in the two factor and the other was ID and my question concerns the ID, making sure the patient is who they say they are. I wasn't asking for a national standard, but some kind of a floor because if a patient is pretending to be someone else and entering one organization's data, that organization can have data from other places. That's scenario one. The other is actually in the PHR that we use with our vendor they now have access to PHR data from all of the places where they've assumed care.

So, there are many ways that in the HIE world data from many sources are being available to an individual claiming to be who that person says they are. So, just as an example of one scenario you could say as the floor, the same level of identity proofing that you use for billing, i.e., proving that you have insurance with this company could be the floor that you set. And I don't think people are going to rely on just saying I am this person and I know the birth date as proof that they're eligible for that health plan, for example. I'm just trying to offer another way of setting a floor that's other than whatever you feel like it for an individual organization.

Deven McGraw – Center for Democracy & Technology – Director
I don't know if any of the other members of the team want to chime in on this. I mean, what are going to do if somebody doesn't have a health plan? Here's the dilemma and I think it's, quite frankly, wrong to characterize the providers that they would do just anything because they're all subject to HIPAA Security Rule requirements where they have to implement reasonable safeguards in granting access to any of the protected health information that is in their stewardship. Whether it originates with them or it originated somewhere else, the patient is viewing it through a portal of an EHR that they offer, they're on the hook for getting this right. Absent that, we didn't think there was, quite frankly, enough evidence that any one approach worked better than the other. When we heard from the VA, they started with in person identity proofing. So at least you'd have the knowledge of the relationship in order to open the portal, but they migrated from that, because they heard from their vets that it burdensome to require them to come in to do this when, in fact, they largely took care of themselves from home. So they figured out a way to both identify and authenticate people into the portal that didn't require an in-home visit, but that gave them the reassurance that they needed as an institution on the hook for meeting security obligations that they could do this.

I think we already have a baseline sort of standard of reasonable and appropriate safeguards that the HIPAA Security Rule provides for us. Whether we layer something else onto that, I think that's why we came up with the set of principles that people ought to consider. That there's, obviously, risk involved here, but there's also the problem of if your risk tolerance level is so high that you set the bar so high that people can't use it, that doesn't meet objectives either. So, that's where we came down on it and I guess I'm reluctant to have you all ask us to come up with a baseline because I don't think, I don't, quite frankly, think it's possible to do so in the right way that will work for everyone.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Ok, Neil!

Neil Calman – Institute for Family Health – President & Cofounder
I have a few questions or comments, I guess. One of the things we've been talking about in our state board around exchange is the need to sort of eliminate the concept of a floor in relationship to what health information exchange does. I thought that's what you were getting at, Paul. But we're basically coming to a conclusion that we need to set a standard for these things that's not a floor, because to the extent that people build on it it interferes with the ability for other entities to enter into the system.

For example, if the floor is two types of authentication and somebody decides that's not enough for them and they really want three factor authentication, then how do they exchange with everybody else because everybody else that's accessing their system is only requiring two factor authentication. So this is happening around consent policy in New York State, it's happening around the authentication stuff where different exchanges have adopted different policies and now that we're talking about a real statewide model these things need to come together and the conclusion is you can't really do floors anymore.

If you're really committed to Exchange you can't really let somebody that's going to participate in the Exchange set higher levels of authentication than everybody else because it's only as strong as the person who's accessing it. And so if they're giving me access and I only require two factor authentication, but I'm accessing their EHR records and they required three factor authentication for their own providers, what does that mean? That's just one issue and I think that's the reason why sort of allowing people to build higher levels of security or higher levels of policies on floors really interferes with our future view. That what we're really trying to do is create standards that are going to allow free flowing access across these barriers, granted that they need to meet certain level. So, that's just one comment.

The other thing is about roles, so you haven't talked much about different people's roles in the system and not just authenticating or identity proofing who the person is that accesses this system, but what do they have access to in the system. Again, this is an issue where I might allow anybody in my organization, any type clinician, social worker, whatever to access clinical records. But somebody else might say only physicians are allowed to access clinical records and only social workers are allowed to access social work records; only mental health professionals are allowed, but my role settings are completely different than that. So I think as we think about exchanging information we also have to think about how we're going to somehow collaborate over establishing roles and I don't really know whether that's something that we're going to get into or move that to 2020?

Deven McGraw – Center for Democracy & Technology – Director
Well, I suspect we will. Really our recommendations to date—and this is also reflective of some of the conversation that we've had this morning—our recommendations to date really have assumed that the model that we have of exchange of data today largely on paper is what we're initially just trying to make digital, right? So, everybody has responsibility for the data that they have stewardship over, that's in their control, that's in their EHRs, which gives them a certain amount of authority about how they address role-based access. Ultimately it's more of a push transaction model, where if the data gets released at all it's consistent with your own institution's policies based on whatever laws that you might need to comply with in your state as well as federal law. What happens as you send it over the border into New Jersey, for example, is going to be up to the recipient's policies and laws.

We have not thought about a set of models, maybe similar to the one that we talked about a little bit this morning with PCAST where we need to set some consistent exchange rules so that the data is more liquid and isn't subject to wildly varying policies on the ability to at least view it, if not view it and access it. And it's a different use case to use the old term. We sort of keep teeing up some important policies, but policies really that are just about digitizing the world that we wish we lived in today or that we live in today in models where there's good exchange of data at least on paper, on facts. And so we're still there because that's the construct of where we're sort of headed in the immediate future, which, quite frankly, are much easier to address when you have a model in front of you that you want to achieve and then you drive the policies around that.

Neil Calman – Institute for Family Health – President & Cofounder
I guess I would just make a recommendation that maybe we could just recommend unless absolutely essential or somebody had some very specific concern that they're addressing that we're not looking at these floors as something that people should build towers on top of, but that we're looking at them as sort of standards. Because the people that we've had trouble integrating into the state Exchange in New York are the people who've built either additional consent requirements or additional identity proofing or authentication requirements on top of what the state has recommended. They've done that because the state's recommendations came after these RHIOs were developed, so now people have to go back and kind of rework this.

So, we don't want to create that again, sort of at a national level. Anyway, that's enough on that. The other question I wanted to ask was about patient choice in terms of their level of concern in the balance between ease of access and the security of their records and whether or not we can't figure out a way to basically say, look, I'm not really worried as much as you are about somebody accessing my records. I want to be able to put in my name and password and that's it. But another person might say I'm really

concerned. There's stuff in my records I wouldn't want anybody to know about and I want to have a token or something else that enables me to provide a higher level of security for my information. I'm wondering if we couldn't build in some sort of recommendation that allows for or suggests that there should be patient choice in the level of security that their information has.

Deven McGraw – Center for Democracy & Technology – Director
We did include in the guidelines that providers could; I thought we did, and maybe we didn't. I'm just rereading what we had here. Because I thought at one point we set the user name and password as the baseline, but providers should consider offering patients who are seeking a bit more in terms of authenticating to a portal to be able to do that. I don't know how easy that is to do. If it's not in here, it's certainly intended to; we can add that if it didn't get in here. It should have. We talked about it and I thought I wrote it. We can add that. This concept of, obviously, this is a set of guidelines, so we're not setting a requirement that you get to pick every aspect of your authentication that you would like, but I do think giving people some choice where you can for more security for people who are nervous about inappropriate access would be idea. So, it was intended to be in here. Thanks for catching that, Neil. I don't know where it went. I'll have that drafted.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I would just put forth a caution about this, which is it's nice to be able to say we want to give patients a choice if they want to have a token or something else to access their record. But providers can only offer that option if the system has the capability to do it and so it speaks a little bit to your issue that standards in fours. It's easy to say we want to do that, but the policy lever that we're using for this part of the discussion is basically certification criteria, which is certification of the EHR, so what are we certified against? And it's being certified against the standard for authentication. And unless you establish a higher standard you don't necessarily have that option to offer the patients.

Deven McGraw – Center for Democracy & Technology – Director
Right, unless you negotiate that with your vendor. So, instead of it being required as part of certification for every EHR it would be—and it actually, now I see it on page five, yeah—we do say in the policy recommendations on authentication that single factor authentication would be a minimum. That providers may want to at least be able to offer their patients additional security such as through additional knowledge-based questions or a token or whatever it is that they want to pursue.

Neil Calman – Institute for Family Health – President & Cofounder
So, are we going to require EHR vendors in certification to provide that? Is that a recommendation that we're making, that similar to what Paul just said, that we would require the EHR vendors to provide that capability?

Deven McGraw – Center for Democracy & Technology – Director
We didn't write that, but if that's what you want to consider; I just wonder.

Neil Calman – Institute for Family Health – President & Cofounder
I'm not making the recommendation, I'm just saying.

Deven McGraw – Center for Democracy & Technology – Director
Yeah, so what we did say, since we had a baseline of user name and password, we did say that the system ought to have the technical capability to thwart either programmatic attacks or an attack from somebody who is unauthorized, but is a single user. So beyond that technical functionality I think the difficulty would be that there are lots of other levels of authentication and ways that you sort of authenticate yourself, such as the one, I think, that we're all familiar with in banking. Which is basically not NIST level two, but kind of in between, which is user name/password and then a question, a knowledge-based question. We actually have some guidance on be careful of those knowledge-based questions because sometimes you could have an inappropriate user who actually has a fair degree of knowledge about the patient, like a former spouse, for example. So, if you're going to go that route, then you pick those questions.

Then there is the hard token, like a smart card or a FOB that generates random numbers or a random number generated to your cell phone. It seems as though there are a lot of different ways to do this and it might be hard to set one standard in certification that would meet the variety of ways that providers might do this, but I'm certainly open to talking to the Standards folks about it. I mean, at least we know, with the DEA rule we have some really clear rules about what's required to authenticate and so the systems can adjust to that; it just seems a little bit more open on the patient space.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Larry?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
So, my flag has been up and down because I've been trying to stay out of the details here because I'm not a security guy, but I have friends who are and they would beat me up if I screwed this up. So, I've decided to sort of limit my comment.

Deven McGraw – Center for Democracy & Technology – Director
I get beat up all the time, Larry.

Paul Egerman – Software Entrepreneur
It's security people doing it.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
That's right, they're ensuring security by making sure there's no one to break security. The specific comment is often organizations, certainly this is the case at Kindred, provide a remote access technology that then is applied to many applications. So the security that we provide as an organization for remote access is not embedded in any one application, but, in fact, is a platform that we make generally available and then based on the user put different apps in that space and might provide single sign on, so they don't have to re-authenticate.

We do require a token currently to get in and we're getting a lot of pushback from physicians about, you know, that blankety blank random number I have to read in the dark; so, I guess my concern is that we not over-engineer the solution here. That the organization has to provide the level of security and they may choose to get it through the portal out-of-the-box from their EHR vendor, but through a lot of other ways they could get that security and to create additional burdens of additional things that need to be certified might be inappropriate. So I guess I want to be careful how we frame this. That we're not as we go into criteria that we don't say the only solution here is for your portal to have this technology embedded in it, but you might choose lots of other approaches and if someone does choose that to minimize the certification burden they're going to have to go through to get that alternate technology certified.

The second piece that really struck me all through this conversation actually brought me back to Farzad's opening comments about the need to communicate better because we keep making references to existing rules and regulations outside of meaningful use. So where there are HIPAA requirements that we should help people understand not just there's a requirement, but there might actually be industry best practice and it's not required for meaningful use that you use industry best practice, but if you want to stay out of the newspaper maybe you should use industry best practice.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Judy?

Judy Faulkner – Epic Systems – Founder
I think this is a good discussion. One of the topics when we had the meetings on the phone last month or so was an interesting one was the two factor identification for remote stuff. I was listening to you, Larry, and thinking part of it is that balance between your physician who needs to access something quickly with your handheld; do you put in two identifications besides your password or just one? I think we ended up with two and I was just kind of curious as to whether those who have used a remote device for accessing

information whether your personal experience would be that besides putting in your name and password, would another one be a burden. Would it slow you down to the point where you'd think I don't want to use that or would it be fine? I'm just curious.

M
I would add a footnote to that; what we're exploring is actually putting a digital certificate on the device, so that there's an initial that user has to go through to get that second factor on their device. Once we put it on their device, then they could sign in with just a user ID and password as long as it was tied to that device.

Paul Egerman – Software Entrepreneur
That works in terms of counting is one of the two factors so, indeed, on a mobile device there are vendors and systems now that do that so what you have to do is, in effect, you have to register the device. You have to sign on a Website or something and say here's my cell phone number or something and it texts you some number and you have to punch in the number; you go through a little process. But then, once that's happened, that device is registered so that counts as one of the two factors that has the certificate. You still have to put in user name and password, but that's how that works.

Deven McGraw – Center for Democracy & Technology – Director
In the letter there is a lot more explanatory text about how we didn't feel comfortable going all the way to where NIST or the DEA rule would be with respect to two-factor authentication. We also, again, suggested, as Paul mentioned, get public comment on this. If it's going to be part of the NwHIN then there's a governance proposed rule, there's a chance to get some more feedback on this. We also suggested that the Standards Committee could provide recommendations on what would be appropriate factors for two factor because it's less than the two factor that NIST would require of the government and it's less than the two factor that DEA would require for e-prescribing of controlled substances. We raised all those same concerns about sort of the balance between ease of access of very important information that sometimes is extremely time sensitive to the important security protections for remote access.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
David.

David Lansky – Pacific Business Group on Health – President & CEO
I just want to say I think you've ended up in the right place, not over-engineering. If I had to go through an additional factor I think I'd get rid of my mobile device. I think there is a real risk of creating too many hurdles for people and just making it too hard to get at information. I think the path you've chosen is a good one.

Neil Calman – Institute for Family Health – President & Cofounder
I have one clarification question, and I think I know what you intend, so the EHR user authentication we talked about when organizations are seeking information that include remote access, you wanted a baseline you included two factors. In the HIE world as part of your routine and counter you may have the opportunity to incorporate things from other organizations and I think you're not proposing at that point to use two factor identification, so it's just a matter of clarification when you're access from a remote area, i.e., on the Intranet, that's what you meant, correct?

Paul Egerman – Software Entrepreneur
That's correct.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Any other comments or questions? Yes?

David Lansky – Pacific Business Group on Health – President & CEO
I thought I heard you say something, Paul, about entity level certification at one point.

Paul Egerman – Software Entrepreneur

Certificate.

David Lansky – Pacific Business Group on Health – President & CEO
Pardon?

Paul Egerman – Software Entrepreneur
It's a certificate.

David Lansky – Pacific Business Group on Health – President & CEO
Certificate. So, in this remote access that Paul was just referring to, is there something about an entity level certificate that needs to accompany this two factor remote access?

Paul Egerman – Software Entrepreneur
No. I understand why there's a question because it's sort of like a little confusing where it's placed in the sequence, but basically the purpose of the certificate is at an entity level related to these push transactions where sometimes one entity sends another entity something. Like lab results come from a commercial laboratory, go directly to a physician or orders go from the physician directly to a lab or an imaging center and having digital certificates for each of those entities helps to facilitate that exchange of information, but does not relate to this two factor authentication process. These are not individual certificates; these are entity certificates that we proposed.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Okay. We're ready for a vote to entertain a motion to approve their recommendations. Okay, second. And all approve? Any object? Any abstentions? Good. Thank you very much, Deven and Paul.

Deven McGraw – Center for Democracy & Technology – Director
Thank you all for a really helpful discussion.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Next we have Information Exchange Workgroup update and I don't know whether it's you or Micky?

Judy Sparrow – Office of the National Coordinator – Executive Director
He is on the phone.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Okay, Micky, great. So, Micky, the stage is yours.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
Thanks, everyone. Sorry I can't be there in person. We just want to give a quick update on the Information Exchange Workgroup activities since the last Policy Committee meeting. You may recall that at the last Policy Committee meeting we presented some recommendations related to the so-called individual level provider directories, which were following on from recommendations that were made and approved by the Policy Committee in December related to the so-called entity level provider directories.

On the recommendations that we proposed at the last Policy Committee meeting related to the individual level directories we got some direction from the Policy Committee to streamline those recommendations a little bit and sharpen them. We are not prepared yet to bring those back to the Policy Committee today. We'll be doing that for the May 11th meeting; in particular, for two reasons.

One is that as we've gone back and started sharpening those recommendations it's been in the context of the conversation that we've been having about meaningful use stage two. I think a number of questions are coming up now as we look at that to try to sort of fit that into an overall perspective on how we want to think about health information exchange going into stage two and stage three. So, we decided that it was better to spend a little bit more time doing that, take a little bit more workgroup deliberation time before bringing those recommendations back to the Policy Committee. So, we'll anticipate bringing the

individual level provider directory recommendations back to the Policy Committee at the May 11th meeting.

The other thing that we've been engaged on now is, as I alluded to, is the consideration of the meaningful use stage two and stage three recommendations and we're doing that on a couple of different fronts. One is detailed line by line commentary on the stage two recommendations that the Meaningful Use Workgroup released for public comment back in January or February I think.

We've submitted one letter already to the Meaningful Use Workgroup that addresses a number of recommendations, the line by line recommendations and our perspectives on those where we have a variety of comments, some of which were of the flavor of supporting them as written. For some of them we recommended to the Meaningful Use Workgroup that they make them more aggressive and in some cases we suggested that they actually pull back on some. So, that was all contained in a letter that we formally transmitted to the Meaningful Use Workgroup last week or the week before I believe.

We're now in the middle of drafting a second letter, which addresses the remaining line by line recommendations that the Meaningful Use Workgroup had released to the public and we anticipate transmitting that to the Meaningful Use Workgroup either next week or the week after. The reason we divided that into two letters was to support the April 5th public meeting that they had to discuss the public comments that they had received on those and we wanted to be able to provide recommendations of guidance on as many of the recommendations we could get to by the April 5th meeting. So, we have a second letter coming that will complete our review of the entire list of recommendations that were put out for public comment.

On a broader front, also related to input to the Meaningful Use Workgroup, we're also then going to start to have some broader conversations within our workgroup, but also want to be able to reach out to the Meaningful Use Workgroup and find out which areas they specifically need input on. Because as we understand from members who are crossing across the workgroups there are a number of areas coming up on the stage two, stage three recommendation side that they are looking to us for some input on, so we want to get some better understanding of that. But from our perspective the things that we need to engage on are one, how to move beyond push transactions. So, as we think about sort of the term that's being kicked around the workgroup is what's the down payment we want to make on the future vision of health information exchange and how do we do that now? So, in particular query response types of exchange, data aggregation for quality measurement and population health are two general topics I think we want to think about as we think about how do you take specific meaningful use stage two, stage three recommendations and have them stimulating the next level of Health Exchange, beyond push transactions.

So, that's one set of considerations that we're going to be taking up. The other, I think, is related to what are the key infrastructure components to enable meaningful use stage two and stage three as we think about these other types of transactions? Provider directories could be one of them, but there could be a number of them that we want to think about. As we think about what those key infrastructure enablers might be the last consideration I think in that is how do we translate those into clinical process types of measures that are specifically labeling that the stage two or stage three objective is you must use this infrastructure. But rather is something about stimulating behavior that improves clinical processes or clinical outcomes but that is able to rely on some key enabling infrastructure to get us to the next level of health information exchange.

So, very sort of abstract kind of concepts there, but I think fundamentally important from our perspective in the workgroup to be able to start addressing directly and providing some concrete input to the Meaningful Use Workgroup as it goes forward in anticipation of the recommendations that I think it's going to be making on May 11th as well.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

All right, questions, comments for Micky and the Information Exchange Workgroup? Not having anything here, so it must have been very clear. So, we'll be hearing your specific recommendations on the individual level provider directory in May?

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
Yes.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Okay, very good. Thank you. Next up is the Enrollment Workgroup update.

Judy Sparrow – Office of the National Coordinator – Executive Director
We have Sam Karp, who is on the telephone.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Okay, great. Hi, Sam.

Sam Karp – California HealthCare Foundation – Chief Program Officer
Well, like Micky, sorry I can't be there with you all in person. I wanted to update you on two things. One, just a very brief update on the activities of the Enrollment Workgroup. Then, secondly, and I believe you have a letter that summarizes feedback that the Enrollment Workgroup was asked to provide to CMS with respect to the proposed federal verification hub service. It's called different names, but it's essentially a response by CMS to some recommendations that were made previously by the Enrollment Workgroup.

So, let me start first with just a brief update. I think as you all know we provided ten recommendations through the Policy and Standard Committees that went to the secretary back in early September. The secretary adopted, with minor changes, those recommendations and they have become part of the requirements and guidance that CMS is providing to the states with respect to the development of health insurance exchanges that are being developed in the states. The Enrollment Workgroup still has three tiger teams working on consumer engagement issues, on business rules and on privacy and security and we hope to wrap up our work in the next couple of months and bring to you a final set of recommendations. I'm not sure they'll actually contain new standards. They may contain some additional guidance that we'd like to present. So, that's the first part of my update, which is just to tell you where we are in terms of our work.

Second, we were asked by CMS to provide some feedback to a set of questions that they provided to us on the usefulness of a federal service that would do verifications. A little bit of background; the Affordable Care Act requires that eligibility be electronically verified in three specific areas: that the Social Security Administration verify electronically that the applicant is a U.S. citizen; that the IRS verify income and that the Department of Homeland Security verify immigration status. During the course of the early meetings that the Enrollment Workgroup had we had public testimony from representatives of Social Security Administration, IRS and the Department of Homeland Security to assess where they are, at least where they were at the time in terms of meeting these requirements. Rather than go over it all with you I can simply say that we were assured by each of the departments that they had the ability to in real time be able to provide electronic verification.

There were issues that they were each working on in terms of quality of data, in terms of use agreements and so on, but that they expected to be able to meet all of those requirements. As a result of the public testimony that we took, included in our initial recommendations were two specific recommendations with respect to verification. One was that in performing these verification assessments we proposed that a standardized set of Web services be used and the second recommendation had to do with the development of what we called at the time a federal reference software model, which CMS is now calling a verification hub or federal hub services. The intent behind our recommendation was that rather each state having to develop its own verification service and connect separate to Homeland Security, Social Security Administration, IRS, that if this were done in a more standardized way it could be more efficient and most cost effective and would not create the need to develop the same thing 50 times over.

So, based on those recommendations CMS is moving forward at least conceptually with this idea of a verification service. And they essentially asked us to provide feedback to them in two areas. One was what did we think about the usefulness of this type of a service to verify consumer provided information? And, secondly, what did we think about the usefulness of such a federal data service to be able to update and maintain information about individuals, particularly with respect to sharing it across states.

I believe you all have the letter there, is that right, Farzad?

Farzad Mostashari – ONC – National Coordinator
That's correct.

Sam Karp – California HealthCare Foundation – Chief Program Officer
So, this is a letter that summarizes the comments that occurred both in a couple of tiger teams and then brought to the full Enrollment Workgroup. Let me just summarize it simply by saying we think that this service as I've described is consistent with the recommendations that we've previously made. We actually think that a verification service that works well is probably the most significant or single most effective thing that can be done to simplify enrollment. That's because if you can take a set of standardized data elements, five or six or ten data elements and verify income, verify citizenship and verify immigration and legal status, that's an awful lot of information that an individual does not have to provide and an awful lot of questions that don't have to be asked as part of an eligibility determination process.

So, we think that the service itself is consistent with what we've recommended in the past. One of the questions to us was did we think that such a service could be used to identify one of the requirements in the Affordable Care Act determines whether an individual has existing federal health insurance provided by FEHB or TRICARE or Medicare. We concurred that we thought that at a federal level this was a service that this hub ought to be able to provide and it was highly desirable. Whether or not this service could identify whether someone has health insurance in another state, particularly Medicaid in another state, we thought was much more problematic. While we thought it would be useful, we thought it would be harder to actually develop given the variation in states, particularly the time frame in which states would enroll or dis-enroll individuals in the Medicaid program and we didn't think it was something that rose to a high level of priority.

There are a number of other recommendations or requests, feedback to specific questions that are, I think, pretty well articulated in the letter. One last thing I want to say and then I'd be happy to answer any questions, that while we as a workgroup were not specifically asked to comment on the consumer relationship with the proposed hub, at a minimum we think that, consistent with other recommendations that we made about the consumer roles. That a consumer ought to be able to see and use and update and correct or, certainly, appeal any information that's returned to the Exchange by this type of a federal hub for verification. We think the consumer ought to be able to be provided with information that's understandable. In one of our recommendations with respect to how rules are determined, we suggested that they be human readable or human understandable and that they be expressed unambiguously. And we think that follows in this case as well, that it will be important for individuals to fully understand what is being said back to them about their eligibility and the basis for being determined eligible or not eligible, whether it's for Medicaid or whether it's for subsidized services.

So, with that, let me stop and I'll be happy to answer any questions you have. Our request here is that you take the feedback and the feedback only and provide it through the right channels to CMS.

Farzad Mostashari – ONC – National Coordinator
Okay, thanks, Sam. Questions, comments for Sam? Larry.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
I seem to be full of comments today. So, two questions come to mind as you're pulling this information together. Was there much discussion about data quality or about identity management? It seems like the issues we have for patient IDs get multiplied when we're looking at this kind of information.

Sam Karp – California HealthCare Foundation – Chief Program Officer
Yes, there's a lot of comment about that, good question. When we had the Social Security Administration in and they shared with us that they are doing data matching now, a pilot project with 26 states for the Children's Health Insurance Program. They are actually, through a set of minimum data elements, they are getting about a 96% match rate, which was pretty good. One of the things that were part of our initial recommendations is the need to really standardize those data elements and our recommendation included using the National Information Exchange Model, NIEM, for those data elements. I know that there's a project underway at ONC right now to develop NIEM standards for those specific data elements, which we think will help increase the incidence of match.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
I guess my only thought would be that 96% still leaves 4% that's a problem and times the number of folks who may be applying that 4% is still a very big number.

Sam Karp – California HealthCare Foundation – Chief Program Officer
It is, it is. Everybody would like to see it increase from that because in the Children's Health Insurance Program a social security number is not required in many states. We think that that accounts for a large part of that 4%.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
Yes, I guess the piece that I would want to make sure is understood and this is not a systems piece, it's a general education piece, is when it comes back with problems that we work with individual on resolving them because the likelihood of identity problems is not trivial and the implications are huge.

Sam Karp – California HealthCare Foundation – Chief Program Officer
No, they absolutely are, but when you consider in most cases today verification is done through paper documents and handled individually, reducing that number takes a tremendous burden off the system, which hopefully will allow the system to be able to focus on that smaller percentage of people who you really have to work with individually.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
Thanks.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
David.

David Lansky – Pacific Business Group on Health – President & CEO
Hi, Sam. I think this is really helpful and I can definitely see the value of it. I have two questions, one of which is similar to Larry's. The letter itself seems to be primarily a technical endorsement of the value and feasibility of it. I just wonder if there's a larger constellation of policy issues, which may not be as much triggered by the immediate applications of this hub that we can already see, but maybe down the line with other applications of the hub as other programs come on line, both federal and state and perhaps others. Once the capability is there will there be other issues around consent, access, re-use and I don't know what? And what all did you talk about as far as a policy framework that surrounds the utilization of this kind of a hub?

And the second question, I know in the case of the Exchanges, in particular, there's an issue of accessing household income, not only individual subscriber income, and there was some discussion I've heard about accessing the state databases. I know you've mentioned that's probably a second generation task for this particular initiative, but as you think about these broader questions of accessing more current income verification or state level databases or household member information as well as the individual patient or enrollee information. Is there another set of issues that we should be thinking about as far as sort of the network of resources that are supportive of the same kind of functionality?

Sam Karp – California HealthCare Foundation – Chief Program Officer

Good questions, David, both. Let me take the first one. There are a number of policy issues, just starting with the consent. At what point in the process is the applicant asked for her or his consent before those data elements are used to verify income or citizenship? And that's an issue that I know that CMS is looking at right now and we're going to be in further conversation with them.

The second policy issue that comes to mind, and we've talked about it some, I've talked with Deven some about it, we talked with Joy about it, and that is the limitation of use of this data, particularly data from Homeland Security. It makes an awful lot of people nervous to have their information being sent to Homeland Security and what happens with the data that's sent after the service has been performed and they've been verified to be lawfully in this country or their immigration status has been verified. And I know that that's a larger issue in the federal government with what happens to information once it's used for a different purpose. We did look at the limitation of use agreements and we're relatively satisfied with, at least presently, how they're structured, but that becomes a policy issue that I think we and others will want to look at further.

With respect to the second question, in terms of all these additional data sources in our letter we identify five or six other data sources that, in some cases, states are required to collect information, but also would provide, as you suggested, more current information about an individual or a family's income. And you know that we're also waiting for CMS and the IRS to define how they specifically will look at and modify the adjusted gross income, but we all know that that's going to look back a year because of the income volatility of a large swath of individuals who will be eligible for coverage under the Affordable Care Act.

We know that a year back look isn't necessarily be appropriate for many people and so being able to look at a lot of the state level wage data that is often much more current, as you suggest, will be important. It's really a matter of what's practical to get done between now and 2014 and so the fact that many of these state databases are all structured very differently; the ability to query against them in a standardized way is going to be quite difficult and is going to take some time. But, it's clearly on our sights as something that's going to be important to do. It's really a sequencing issue at this point.

David Lansky – Pacific Business Group on Health – President & CEO
Okay, just to follow up; just one more thing about the first question, Sam. Does your workgroup contemplate another letter that would more specifically lay out a policy framework for this hub functionality?

Sam Karp – California HealthCare Foundation – Chief Program Officer
I don't think we've discussed a letter necessarily. I know we discussed looking at it. One of the issues with the workgroup and I'll ask Farzad to comment about this, the workgroup was structured much more as a technical workgroup than a policy workgroup and often in our discussions we've been counseled to not deal with policy issues. As you all know quite well, you can't deal with technical issues in isolation, but there has been a tension in the group based on the charge that we received. Farzad, do you want to help me with that a little bit?

Kristen Ratcliff – ONC
He's not on the phone, but this is Kristin Ratcliff. I've been helping support the Enrollment Workgroup and Sam is exactly right that our charge in Section 1561 was to produce streamline standards and protocols. We've accordingly tried as much as possible to stay out of the policy realm, recognizing that as policy decisions are made by CMS and others throughout the department that we can then take that information and feed it into our process of trying to get to a more detailed level.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
All right. Any other comments or questions from the Committee? Nothing. Thank you very much for the update, Sam, and for the work on this important work that is instrumental to the state exchanges getting set up. You need this letter to be approved, is that correct, Sam?

M

He needs the letter to be approved so that it can be formally translated up the chain to CMS.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Okay. Someone want to? Okay, Paul, and second? All in favor? And opposed? Abstain? Good, thank you and you have your letter transmitted, Sam.

Sam Karp – California HealthCare Foundation – Chief Program Officer
Thanks, Paul. Thanks, everyone.

Paul Egerman – Software Entrepreneur
Paul, I just wanted to make one more comment on this. It's interesting, as you look at the concept of the Insurance Exchange, somehow we have this sense that we keep all the healthcare clinical data separate from all of the insurance and payment information. It's just like these two separate worlds and we have this thing now that's called the Insurance Exchange, which everybody gets mixed up with Information Exchange, because it has the same initials. So, an interesting thing to think about is well maybe we can get rid of a lot of the confusion by actually starting to think about them the same way. That maybe these shouldn't be viewed as two separate things, that maybe some of the identity issues that Larry raised are being addressed a bit by the Insurance Exchange and there's a way to leverage that information on the clinical side.

Now, there's a lot of interesting policy hurdles to pass to do that, but it's just an observation. It doesn't have to be the case that they're two separate worlds, especially when we go to accountable care organizations, which are starting to be entities that are somewhere in the middle.

Tony Trenkle – CMS – Director of OESS
Paul, I couldn't agree with you more and we've actually been looking at that at CMS to some extent, also with ONC, so you're totally on target.

Sam Karp – California HealthCare Foundation – Chief Program Officer
Paul, you're again on target and I know that there are a number of states that are looking at that as well.

Deven McGraw – Center for Democracy & Technology – Director
I think it's hard in the absence of knowing exactly what that's going to look like to tie to it yet, but it certainly does suggest that as these programs continue to evolve and get finalized we look to build the synergies among them. So that we're not replicating the same thing over and over again and allowing them to work together.

Paul Egerman – Software Entrepreneur
It's true we don't know what it looks like, but we know that there are going to be statewide insurance exchanges and that we know that we've been building somewhat statewide information exchanges. It just seems like we should take advantage of the fact that they have the same initials and they're statewide, but also have it seems like some of the same data, that it might be something to leverage.

Paul Egerman – Software Entrepreneur
So, I think although we made a big movement towards universal coverage we aren't quite there yet and some of the tension is because you don't want to mix the clinical state with the insurance status. I mean, I think that's some of the concern, right, from an individual's point of view.

Paul Egerman – Software Entrepreneur
Well, again, there are a lot of policy hurdles to cross and that is one of them. But, again, you look at the issue of identity assurance and if the statewide exchanges are addressing that they're basically creating a database that identifies all the citizens in their state and there might be a lot of value in being able to leverage that.

Deven McGraw – Center for Democracy & Technology – Director

Like in terms of authentication broker, it's either a database or something that you can rely on to do your identification and authentication, depending on what it is.

M
And because these are HIPAA protected data, the eligibility information, the same policy issues around authentication, consumer access, exist. In fact, in this administrative world are looking much more to the clinical work that's been done as guidance.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Great comments. Okay, I think we're up for our final panel, which has to do with the Certification and Adoption Workgroup update. Marc Probst.

Marc Probst – Intermountain Healthcare – CIO
Thanks, Paul. If I talk really slowly we can use up the last 45 minutes. The Adoption and Certification Workgroup was asked to take a look at usability. Paul is pretty engaged in a bunch of other workgroups so we asked Larry Wolf, actually, to co-chair that group. I want to just say that Larry has done a lot of work in helping to prepare for this particular hearing on usability, and Judy as well, while she was trying to deal with a government shutdown and get all these things going over the last week, so we've had a lot of support. But just briefly, I wanted to make you aware that this year is happening. It's happening next week on the 21st. I think we have a very strong panel of people coming to talk to us and really the focus is on the overall effectiveness of EHRs as it relates to usability, understand some of the safety issues associated with usability and the use of EHRs and just get what are some compelling issues associated with usability. So, it should be a pretty interesting panel.

We also are going to look at testing, what kind of testing can be done relative to usability, or measurement, how do you measure what good usability is? We're trying to get both the clinician perspective as well as the patient or the family end user perspective on usability and also take a look at some of the disability issues associated with usability realizing that the spectrum of users is just huge in what we're talking about relative to this clinical information. So, the actual panelists they're listed there on the agenda. The agenda, has it been sent to everyone? Okay, so everyone has that agenda and we're just looking forward to a very interesting hearing again next week. I don't know if there are any questions on that, but we did want to make you aware of that.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Great. Thank you, Marc. Before we turn to public comments, I just want to acknowledge the new leadership of Farzad coming in in the role of National Coordinator. I want to take the same opportunity to recognize the tremendous work of ONC staff. It's just incredible, the amount of work that's been going on and, obviously, went on in the office and also in CMS. But also someone to special note is, you know, we started out saying this is our 22nd meeting. There's not only been 22 meetings, there have been multiple times that, and there is no meeting that doesn't happen without Judy Sparrow. So, if there's a glue that holds us all together, these things we hear about hearing after hearing and they just happen and they sometimes happen in a matter of a couple of weeks, something happens to make it so and Judy's a lot of that, so that you very much.

Okay, we'd like to open it up to our public comment.

Judy Sparrow – Office of the National Coordinator – Executive Director
If there is anybody in the room who wishes to make a comment, please queue up at the mic and if you're on the telephone you can just press star one and if you're on your computer you'll need to dial 1-877-705-6006. We have Dan Rode at the microphone.

Dan Rode – AHIMA – VP Policy & Government Relations
Good afternoon, Dan Rode, AHIMA. And I'd echo all the comments about Judy and the rest of you because I know how much work it is. Just look at the calendar and ten multiply it by thousands, a lot of time. I'd like to thank you for the discussion this morning, especially in the alignment. Alignment is extremely important right now and while you have a goal with meaningful use in the achievement of

electronic health records, our providers are very much under the gun to go with other actions, including the introduction and implementation of ICD-10CM and PCS.

I'd like to urge you to consider that as you look at meaningful use because the data that will be available with the ICD code set is very much needed for some of the things that we're trying to come up with. Already we're beginning the process of converting the NQF measures into ICD-10 codes so they can be used when the time comes and as you consider your timeline think about the idea of coming in with ICD-9 based factors, January 1 of 2013 and then changing them October 1st of 2013. I really strongly urge you to think about how we might be able to work with those activities. Likewise we're just beginning the early stages of the mapping or crosswalks between SNOMED CT and ICD. We're already beginning discussions that have come out of some other alignment meetings about how we can work with the National Library of Medicine to make sure that some of the basic SNOMED activities that reflect meaningful use could be mapped to the ICD-10 codes.

So, all of these deserve your consideration. If there is any information that we can provide in this way, please let us know. But it is good to hear that across the government we're now hearing about alignment and we hope that all the goals and objectives within HHS can be achieved. Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, Dan. And we have Robin Raiford from Allscripts on the telephone.

Robin Raiford – Allscripts – Executive Director, Federal Affairs
Hi, this is Robin Raiford. I would certainly like to echo about Judy Sparrow and I hope that if there ever is a government shutdown she's essential personnel and has to come in to keep it moving and glad we didn't have to worry about not having this meeting today. I just wanted to give a brief comment about two factor authentication, so you're aware that it's definitely out there today, out there in many EHRs and e-prescribing systems because it is required in the state of Ohio. The Ohio State Board of Pharmacy requires it so any EHR vendor or e-prescribing that sells and has clients in Ohio already has that in their system and I just wanted to put that in the record.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, Robin. Any other comments in the room? All right, with that I'll turn it back to Dr. Tang.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Okay, thank you for sticking it out with us. Fortunately, we finished earlier than we thought, but thank you so much for all of the rich discussion we've had in every meeting and thanks for all the work that goes on behind the scenes in presenting these ideas and updates. Thanks.

Public Comment Received During the Meeting

1. Given the huge benefit that would be reaped by having a national authentication of healthcare providers, a healthcare certificate authority would seem very beneficial to providers, i.e. those with a license. This could be used for eRx (including controlled substances, if the DEA was engaged), authentication to systems, encryption/signature of email over a public network, signature of orders in a system, etc.). A single, centralized, federal healthcare IT certificate authority, could be harmonized with NPIN and DEA authorization. This could be run at the state level for administration/issuance and identity proofing in conjunction with existing mechanism for identify and credential verification. If a provider has a digital certificate, that becomes part of their license (e.g. the electronic version of the license could be signed with both the providers public key and the state licensing authority's private key), and those without can be issued one as part of the license process and its associated id procd (Use of certificates

doesn't exclude use of out-of-band passwords, etc. but makes all methods of authentication better/more secure).

2. A comment was made that the PCAST review group could not find any implementation of the concepts in PCAST. While it is not a gigantic scale of implementation, the GRID implementation of caBIG (cancer Biomedical Informatics Grid) is an example that illustrates complex search across dissimilar but GRID-aligned databases.

3. What are the reservations with strictly going with Option 2? Given the option allows both for providers to keep the momentum going whilst giving enough time to ensure for Stage 2 planning, certification requirements, etc., HIE development, and take into account all the other health reform effort provider requirements that are also evolving, it would seem it would be the optimal option. Further, it is simpler, cleaner, than the Stage 2a and Stage 2b option. I am very interested in hearing what Tony and HITPC members feeling on this as perhaps we are missing something.

4. I think there is an absence of an effort to educate the U.S. population about the importance of these efforts. In providing my comments, please mention that I am a member of the Biomedical Informatics Think Tank. Can the requirements for Stage 2 be integrated with a successful ICD-10 implementation such as providing new quality measures based on ICD-10 information. HIT Policy needs to be focused on how we use this volume of data at least by Stage 3. We need to be setting the stage for this with secondary use requirements in Stage 2. ACO requires strong support for comparative effectiveness research. The Health IT effort regarding MU should be focused on improving secondary use and privacy and security required to provide information to researchers for improving care. How will various options for a UEL standard be tested? I agree that the large operational tests need to be run to resolve policy and feasibility concerns. We have posted a possible solution to privacy and security concerns that demonstrates a possible solution for secure aggregation without the need for a universal unique identifier, which is an important component of the PCAST report. http://bit.ly/fzfjc9 This is the type of project that should be tested. Are there any options for the De-identified aggregate data search and retrieval. Note that two of the objectives for information to transform healthcare require the ability to do research on care and outcomes. This stresses the need to provide more support for HIT policy to support needs of research. This, I think, stresses the importance of the New Exchange Architecture. How do we get our proposals considered for a UEL specification? We also have technology for secure aggregation (see http://bit.ly/fzfjc9) which we would like for consideration by ONC. It sounds like you are pursuing specific demonstration projects for a New Exchange Architecture, but I do not know the mechanisms to get proposals funded, or what types of proposals you would like to see.